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ABSTRACT

This document presents findings of the Presidential Commission on the Human Immunodeficiency Virus (HIV) epidemic. The executive summary lists 20 major findings and recommendations which together comprise a comprehensive national strategy for managing the HIV epidemic. The commission recommends: (1) replacement of the obsolete term "AIDS" (Acquired Immunodeficiency Syndrome) with the term "HIV infection"; (2) early diagnosis of HIV infection; (3) increased testing to facilitate understanding of the incidence and prevalence of HIV infection; (4) treatment of HIV infection as a disability under federal and state law; (5) stronger legal protection of the privacy of HIV-infected persons; (6) immediate implementation of preventive measures such as confidential partner notification; (7) prevention and treatment of intravenous drug abuse; (8) implementation of drug and alcohol abuse education programs; (9) establishment of federal and state scholarship and loan programs to encourage nurses to serve in areas of high HIV impact; (10) extension and expansion of the National Health Service Corps; (11) aggressive biomedical research; (12) more equitable and cost-effective financing of care for HIV-infected persons; (13) addressing the concerns of health care workers; (14) federal assurance of the safety of the blood supply; (15) undertaking all reasonable efforts to avoid transfusion of another person's blood; (16) development and implementation of education programs; (17) addressing the problem of HIV-infected "boarder babies;" (18) addressing the problem of high-risk adolescents; (19) addressing ethical issues raised by the HIV epidemic; and (20) support and encouragement of international efforts to combat the spread of HIV infection. The 12 chapters of this report present these recommendations in greater detail. Ten appendices of relevant materials are included. (NB)

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Report of
THE PRESIDENTIAL COMMISSION
on the
HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

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June 1988

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Report of
THE PRESIDENTIAL COMMISSION
on the
HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

Submitted to
The President of the United States

June 24, 1988

"No man is an Iland, intire of itselfe . . .
Any man's death diminishes me,
because I am involved in Mankinde."

—John Donne
(1573–1631)

LETTER OF TRANSMITTAL

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June 24, 1988

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of all members of the Presidential Commission on the Human Immunodeficiency Virus (HIV) Epidemic, I submit our final report.

One year ago, by Executive Order, you created an advisory commission to investigate the spread of the HIV and the resultant acquired immune deficiency syndrome (AIDS). In so doing, you tasked the Commission to advise you on the public health dangers, including the medical, legal, ethical, social, and economic impact, of the epidemic. You also asked the Commission to recommend measures that Federal, State, and local officials could take to protect the public from contracting the HIV, assist in finding a cure for AIDS, and care for those who already have the disease. You asked that the final report be submitted no later than June 24, 1988. By unanimous agreement of all its members, this report is believed to have fulfilled the requirements outlined in your Executive Order.

Your decision to take one year to develop a comprehensive national strategy to deal with the incredible complexity of the HIV epidemic was sound. In retrospect, it could not have been effectively developed in less time. In more than 40 hearings, the Commission listened to testimony from over 600 of the most knowledgeable witnesses that could be assembled on the HIV epidemic. The complexity of issues surrounding the HIV is exemplified by the nearly daily development of new scientific information about the virus which will continue to demand frequent review by officials in the public and private sectors.

Mr. President, you afforded the Commission an unusual opportunity to view contemporary American society through the lens of the HIV. We saw firsthand: the frightening specter of drug abuse and its relation to the spread of the virus; an overly burdened and unnecessarily costly health care system; a drug development system unresponsive to the fast-changing unknowns surrounding this epidemic; absence of integrated health education and health promotion programs in our schools; an increasingly litigious and adversarial relationship between providers and consumers of health care; and a society in which some members were still too quick to reject, deny, condemn, and discriminate, resulting in a situation that neither bodes well for the individual nor the public health when dealing with this epidemic.

But what we also saw firsthand was the spark of human spirit which rises high when faced with the gravest of human tragedies. We saw incredible goodness across the nation and a fundamental compassion, expressed by thousands of Americans, from health care professionals to hospice volunteers to local firemen, police, and emergency workers. We heard from young people who daily demonstrate personal bravery and integrity in standing up for their HIV-infected classmates who have been victims of the vilest of attacks by bullies inside and outside their schools. We heard from business leaders, community-based organizations, church and other humanitarian groups who have refused to succumb to the overload of work placed on them or the same old tired bureaucratic obstacles thrown in their way at every turn as they move to meet daily living needs of HIV-infected persons.

We found the HIV epidemic, then, to be much more than a medical crisis or a public health threat. While we found it a grave tragedy, we also saw the HIV epidemic as an opportunity to confront and begin to solve many of the problems our society faces. We saw an opportunity to begin to eliminate flaws in our health care system resulting in a better life for all Americans; we saw an opportunity to begin to educate our young people about their own human biology so that they can better appreciate the unique worth and dignity of themselves and others; we saw an opportunity to begin to eliminate discrimination against persons with HIV infection, as well as persons with other disabilities and illnesses, and embrace them as part of the mainstream of American life; we saw an opportunity to begin to turn the goodness that is out there, just waiting to be harnessed into an unbeatable army against this viral enemy that has captured early ground.

It is our hope, Mr. President, that you will: use our report as your national strategy; harness the goodness that awaits your effective leadership; continue to advance the nation in conquering the virus; and lead us to take advantage of waiting opportunities for more healthy and wholesome lives.

Sincerely,

James D. Watkins

James D. Watkins
Admiral, U.S. Navy (Retired)
Chairman

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EXECUTIVE SUMMARY

The Human Immunodeficiency Virus (HIV) epidemic will be a challenging factor in American life for years to come and should be a concern to all Americans. Recent estimates suggest that almost 500,000 Americans will have died or progressed to later stages of the disease by 1992.

Even this incredible number, however, does not reflect the current gravity of the problem. One to 1.5 million Americans are believed to be infected with the human immunodeficiency virus but are not yet ill enough to realize it.

The recommendations of the Commission seek to strike a proper balance between our obligation as a society toward those members of society who have HIV and those members of society who do not have the virus. To slow or stop the spread of the virus, to provide proper medical care for those who have contracted the virus, and to protect the rights of both infected and non-infected persons requires a careful balancing of interests in a highly complex society.

Knowledge is a critical weapon against HIV -- knowledge about the virus and how it is transmitted, knowledge of how to maintain one's health, knowledge of one's own infection status. It is critical too that knowledge lead to responsibility toward oneself and others. It is the responsibility of all Americans to become educated about HIV. It is the responsibility of those infected not to infect others. It is the responsibility of all citizens to treat those infected with HIV with respect and compassion. All individuals should be responsible for their actions and the consequences of those actions.

Developed in the full Commission report are nearly 600 recommendations to prevent further spread of the virus, manage care of those infected with HIV, and enhance our efforts to discover a cure.

The urgency and breadth of the nation's HIV research effort is without precedent in the history of the federal government's response to an infectious disease crisis. However, we are a long way from all the answers. The directing of more resources toward managing this epidemic is critical; equally important is the judicious use of those resources.

For the reader who does not have the time to review all the material which follows, the Commission has prepared a list of its 20 most important findings and recommendations, no one of which can stand alone or be ignored. These will be detailed in the body of the report, and together comprise a comprehensive national strategy for effectively managing the HIV epidemic.

- The term "AIDS" is obsolete. "HIV infection" more correctly defines the problem. The medical, public health, political, and community leadership must focus on the full course of HIV infection rather than concentrating on later stages of the disease (ARC and AIDS). Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection efforts must now be focused on early HIV reports, while still collecting data on symptomatic disease.

- Early diagnosis of HIV infection is essential, not only for proper medical treatment and counseling of the infected person but also for proper follow-up by the public health authorities. HIV infection, like other chronic conditions -- heart disease, high blood pressure, diabetes, cancer -- can be treated more effectively when detected early. Therefore, HIV tests should be offered regularly by health care providers in order to increase the currently small percentage of those infected who are aware of the fact and under appropriate care. Since many manifestations of HIV are treatable, those infected should have ready access to treatment for the opportunistic infections which often prove fatal for those with HIV.

- Better understanding of the true incidence and prevalence of HIV infection is critical and can be developed only through careful accumulation of data from greatly increased testing. Quality assured testing should be easily accessible, confidential, voluntary, and associated with appropriate counseling and care services. At the present time, a relatively small percentage of those infected with HIV are aware of their infected status. For their own protection and for the protection of those not infected, strong efforts should be made to provide easily accessible voluntary testing. Many of the detailed suggestions in the report with respect to testing are directed toward increasing this percentage.

- HIV infection is a disability and should be treated as such under federal and state law in the public and private sectors. Fear has led to discrimination against persons known to be infected. This reaction is inappropriate. Infected persons should be encouraged to continue normal activities, such as work or school, and live in their own homes as long as they are able. The average time between infection and clinical symptoms is now thought to be seven to eight years -- years which should be productive.

- Stronger protection is needed in federal and state law to protect the privacy of those with HIV, with significant penalties for violation of confidentiality standards, yet with a list of necessary exceptions clearly defined in the statutes. These exceptions are listed in detail in Chapter Nine of our report, in the section on Confidentiality.

- Some preventive measures must be undertaken immediately.
  —Public health authorities across the United States must begin immediately to institute confidential partner notification, the system by which intimate contacts of persons carrying sexually transmitted diseases, including HIV, are warned of their exposure.
  —Agencies which license and certify health care facilities must move immediately to require every facility to notify all persons who received blood transfusions since 1977 that they may have been exposed to HIV and may need testing and counseling.

- Prevention and treatment of intravenous drug abuse, an important facilitator of the HIV epidemic, must become a top national priority. Increased law enforcement efforts to interrupt the supply of drugs must be coupled with greatly expanded treatment capacity, with the goal of treatment on demand, to restore addicted individuals to healthful living.

- Use of other illegal drugs, as well as abuse of alcohol, are facilitators in the spread of HIV by impairing judgment and depressing the immune system. Federal and state efforts to limit HIV spread must contain major components in these areas. Drug and alcohol abuse education is essential for all school children, adolescents, and minorities as well as for all other Americans.

- New federal and state nursing scholarship and loan programs need to be enacted immediately to encourage nurses to serve in areas of high HIV impact, as well as to address the nursing shortage which impedes efficient health care delivery in all other areas. Nurses will provide the major portion of care, both inside and outside the hospital setting, to those with HIV. There is currently a severe nursing shortage, which is only projected to grow worse over the next decade.

- The National Health Service Corps, which places health care professionals in medically underserved areas, is currently slated for termination, but should be extended and greatly expanded. The health care industry should give special consideration to recruiting minority health professionals.

- Aggressive biomedical research is the key to unlocking the mysteries that surround finding a vaccine and cure for HIV. Greater administrative flexibility must be given to the National Institutes of Health to pursue its research goals. Liability obstacles must be removed, and clinical trials greatly expanded to include a broader spectrum of the infected population.

- More equitable and cost-effective financing of care for persons with HIV needs to be examined through a series of new or expanded demonstration programs involving federal and state government subsidy of private insurance premiums for needy patients and greater contribution to risk pools. It is important to move toward an organized system of care, with case management as a principal tool to control costs and provide quality care.

- Concerns of health care workers need to be better addressed by all levels of government as well as the private sector. All of those in the health care delivery system, ranging from the ambulance driver and other emergency "first responders," to physicians, nurses, dentists, lab technicians, social workers, chaplains, and allied health care workers, to obstetricians and surgeons performing invasive procedures, should be provided with complete information about HIV, adequate protective materials, and a safe working environment in which to provide comprehensive and compassionate care.

- Safety of the blood supply needs to be continually assured by the federal government. High priority should be placed on the Food and Drug Administration (FDA) test approval for new, less time-consuming HIV detection tests. Additionally, a restructured blood products advisory committee needs to work with FDA to continuously examine mechanisms that will protect our blood supply.

- In health care facilities, all reasonable strategies to avoid a transfusion of someone else's blood (homologous transfusion) should be implemented by substituting, whenever possible, transfusion with one's own blood (autologous transfusion). Currently available techniques of autologous transfusion include predonation of one's own blood, recirculation of one's own blood during surgery (intraoperative autologous transfusion), blood dilution techniques (hemo-dilution), and post-operative collection for retransfusion (post-operative salvage). Health care facilities should offer aggressive in-service training to their staff on these procedures, and informed consent for the transfusion of blood or its components should include an explanation of the risk involved with transfusion as well as the alternatives to homologous transfusion.

- Education programs must continue to be developed and implemented for the near term, and for the greatest possible positive impact on the next generation. Age appropriate, comprehensive health education programs in our nation's schools, in kindergarten through grade twelve, should be a national priority.

- The problem of HIV-infected "boarder babies" is one of the most heartrending the Commission has encountered. These children live their entire brief and tragic lives in hospital wards, with only doctors and nurses as family. The expected 10,000 to 20,000 HIV-infected births by 1991 also call attention to the critical need for foster homes. Unless the problems of the disadvantaged are addressed, the HIV epidemic will continue to make inroads into these populations and we will see large increases in both pediatric and drug-related HIV disease.

- The problems of teenagers, and especially runaway youth, that place them at increased risk for HIV exposure must be aggressively addressed. The spread of HIV within the heterosexual population should be better defined and accurate information communicated to the general public. Inaccurate and misleading statements suggesting that HIV cannot be spread through heterosexual activity are unwarranted.

- The HIV epidemic has highlighted several ethical considerations and responsibilities, including:
  —the responsibility of those who are HIV-infected not to infect others;
  —the responsibility of the health care community to offer comprehensive and compassionate care to all HIV-infected persons; and
  —the responsibility of all citizens to treat HIV-infected persons with respect and compassion.

- International efforts to combat the spread of HIV infection should be encouraged and assisted by the United States, through our research community and our national contribution to the World Health Organization and the Global Programme on AIDS.

The Commission believes that if the recommendations in this report are fully implemented, we will have achieved the delicate balance between the complex needs and responsibilities encountered throughout our society when responding to the HIV epidemic.

CHAPTER ONE: INCIDENCE AND PREVALENCE

Late in 1980, small numbers of patients in several widely separated locations sought treatment for an unusual pattern of disease symptoms. In all cases their physicians found that even the most aggressive treatment proved ineffective in controlling the unusually virulent infections. When conferring with colleagues across the country, the physicians treating these persons found that similar patients were appearing elsewhere, often in small patient clusters, with identical patterns of disease and patient histories. Many patients had Kaposi's sarcoma, a skin lesion usually benign, but in these patients aggressively malignant. Others had *Pneumocystis carinii* pneumonia, a rare lung infection. Many patients had both, and all were unresponsive to treatment and rapidly died.

Because so many of these patients also had sexually transmitted diseases, including parasitic and fungal infections, and had histories of multiple other conditions, such as hepatitis or drug use, it was difficult to isolate what was making them critically ill. As time passed and the patient population increased, medical researchers suggested that the cause was a specific combination of several infectious diseases. Those who thought the cause was a single agent suggested cytomegalovirus, a new form of syphilis, or a rarely seen parasite that irreversibly damaged the immune system. Still others felt that this disease might be the result of an organism never before seen: a new virus.

Modeling AIDS

As the first cases of acquired immune deficiency syndrome (AIDS) were identified, nationwide surveillance activities were initiated to monitor the spread of the disease. Through surveillance activities, public health officials are able to monitor disease trends and determine what preventive mechanisms will be most effective to alter the spread of infection. For surveillance data to be valuable, physicians, laboratories, and other members of the health care system must uniformly report disease information for centralized collection. In this way, incidence (the number of new cases and the rate at which disease is increasing over time), and prevalence (the total number of existing cases) can be calculated. Both incidence and prevalence are usually stated as rates per 1,000, 10,000 or 100,000 of the population being studied. The prevalence rate is the percent of the population affected. By 1982, a case definition had been developed to identify the range of manifestations of AIDS and physicians were urged to report any cases to the Centers for Disease Control (CDC) through their local or state health departments. Nationwide reporting allowed for the collection of extensive data on individuals with the disease. A major portion of the surveillance activities and the epidemiologic study was conducted by the Epidemic Intelligence Service (EIS), a specialized branch of CDC, in conjunction with state and local health departments and the regular CDC program staff. These public health officials began extensive patient interviews, which:

- led to identification of probable routes of infection, assisting in the eventual determination of cause.
- facilitated monitoring the distribution of cases throughout the population.
- alerted the medical and public health communities to the presence of an emerging crisis.

The case definition of AIDS has undergone revisions, and in September 1987, the new definition was expanded to include wasting syndrome and central nervous system manifestations, increasing the number of reportable cases. As of June 6, 1988, 64,506 cases of AIDS have been reported to CDC. CDC epidemiologists aggregate the total number of cases and categorize them by the presumed or implicated mode of transmission, sex, age, racial or ethnic group, state, and in some cases, city of residence. This information is published in CDC's *AIDS Morbidity and Mortality Weekly Report (MMWR).*

Modeling HIV Infection

Disease surveillance began early in the epidemic, before the human immunodeficiency virus (HIV) had been identified or isolated, and before it was known that there could be a lengthy period of infection prior to illness. Because at that time it was possible to identify only those individuals in whom disease was far enough advanced to be symptomatic, monitoring the epidemic meant monitoring disease, rather than monitoring infection. The early concentration on the clinical manifestation of AIDS has had the unintended effect of misleading the public as to the extent of the infection in the population, from initial infection to seroconversion, to an antibody positive asymptomatic stage to initial indicative symptoms to full-blown AIDS. Continued emphasis on AIDS has also impeded long-term planning efforts necessary to effectively allocate resources for prevention and health care. Decisions on who will receive care, and whose costs will be covered, focused only on those most seriously ill. Continuing to use only the term "AIDS" to make treatment, reimbursement, or prevention program decisions is anachronistic and a policy we can no longer afford.

While it is of value to continue monitoring diagnosed AIDS cases, public policy and prevention efforts should be based on an understanding of the extent and distribution of HIV in the population and on the rate at which new infections occur. This is especially critical in dealing with HIV, for which the average length of time between infection and diagnosis is at least eight years, according to the Institute of Medicine.

In 1986, during a Public Health Service conference in Coolfont, West Virginia, public health experts, using limited data, estimated the number of persons in the United States infected with HIV from one million to 1.5 million. Since that time, additional data have become available, particularly on the size of certain population groups and the HIV prevalence in populations at higher risk of infection.

Current knowledge of HIV prevalence is limited by the relatively small proportion of the potentially infected population who have been tested, either as part of specially organized research/surveillance studies or as individuals concerned about their own possible infection. It is also limited by a lack of uniformity in reporting procedures, specifically, from physicians and laboratories to states, and from states to CDC. It is critical that CDC begin now to collect HIV infection data from the states, not just case reports.

Based on the accuracy of the data and the validity of assumptions made in mathematical modeling, the estimates being published by the Public Health Service may be very close to the truth, or an over- or underestimate. The science of mathematical modeling and its use in the HIV epidemic is discussed by the Institute of Medicine in its recently updated report, *Confronting AIDS.*

The success of any disease or infection surveillance effort is dependent upon coordination at the national, state, and local levels and the sharing of resources and expenses. Radically differing estimates of incidence and prevalence have led to public confusion and distrust. Further, it requires public confidence in the government's goals and intentions and in efforts made to protect privacy and maintain confidentiality. The public health profession has a long tradition of respectful, confidential handling of sensitive data and of affected persons; those currently holding public health posts should be striving to build public confidence by stressing the profession's traditional adherence to this standard.

A further problem has been public concern about test accuracy and reliability. These have been addressed, and experts agree that the current sequence of tests used to detect antibody against HIV, when performed under well controlled conditions in good laboratories, yield both a sensitivity and specificity of greater than 99.8 percent.

All states are currently gathering some HIV prevalence information. At public and private HIV testing sites, sexually transmitted disease clinics, drug rehabilitation programs and various other health care delivery settings, individuals have the opportunity to be tested. Data on infection rates among those who use the services at these sites are being collected and in some cases reported to a central point. A number of states require the reporting of any identified case of HIV infection, and others are considering such a requirement. Until CDC changes the focus of data collection from diagnosed AIDS cases to HIV infections, effectiveness of planning and intervention will be limited.

At President Reagan's persistent direction, CDC has undertaken a massive project of HIV surveillance and data collection. The family of surveys and studies that are components of this project are urgently needed and are designed to gather a variety of data from a cross section of geographical locations and population groups. These surveys include testing of voluntary participants from specified settings either on a confidential or anonymous basis and, in a sentinel hospital survey, testing of unidentified blood samples from groups of interest. Pilot studies for a proposed nationwide household infection prevalence survey are a major part of this project. However, the complete results of these studies will not be available until 1991. Apart from this extraordinary effort, much will be learned from ongoing state, local, and private testing when CDC institutes HIV infection data collection from the states instead of limiting its surveillance to diagnosed AIDS cases.

As of March 1988, CDC acknowledged that a precise statement of the prevalence and rate of spread of HIV infection in the general population is still not available. Most analysts concur with CDC that, based on presently available data, the best estimate of seroprevalence is one million, with a range of up to 1.5 million. Repeatedly, witnesses before the Commission agreed that every reasonable effort should be made to increase the precision of this number, and of the rate of infection within specific population groups.

Section I. National, State, and Community Leadership

Obstacles to Progress

The Commission has identified the following obstacles to a nationwide effort to improve the public's response to and participation in programs designed to quantify the HIV epidemic at the federal, state and local levels:

- Continued focus on the label "AIDS," contributing to lack of understanding of the importance of HIV infection as the more significant element for taking control of the epidemic.
- Lack of strong CDC leadership in the public health community for obtaining and coordinating HIV infection data.
- Lack of uniform and strong anti-discrimination laws protecting those infected with HIV.
- Excessive concern about potential problems with testing programs and reporting systems.
- Inadequate counseling resources to assist those tested makes many support and interest groups reluctant to recommend widespread HIV testing.

RECOMMENDATIONS

To respond to these obstacles, the Commission recommends the following:

1-1 Appropriate federal, state, and local agencies must enact, execute, and enforce anti-discrimination laws within the context of HIV as a handicap.

1-2 The Centers for Disease Control must provide clear direction for expanded and improved surveillance, including endorsement and support by national leaders, other federal agencies, and state and local leaders.

1-3 States should require reporting of HIV infections. This information should be given to the Centers for Disease Control in appropriate form for statistical analysis, without identifiers.

1-4 National, state, and local leadership must work cooperatively to make any HIV testing programs useful as data sources for surveillance.

1-5 All public health agencies must select and use terminology carefully to make the public more aware of the importance of the entire spectrum and implications of HIV infection.

1-6 In all federal agencies all relevant job and program titles should clearly reflect HIV infection as the target of concern.

1-7 Public health officials should provide education, training, and funding resources to expand greatly the use of counseling directly linked to any testing program.

Section II. Public Health System

The HIV epidemic has had a considerable impact on the federal and state public health systems. There is not adequate staff at any level to respond to this crisis. Both accuracy and reliability of the data collected through the public health system, and upon which researchers, health care planners and communities rely and base decisions, are crucial. Diligence in the reporting of each case of AIDS is needed, along with immediate development of a mechanism for overall HIV infection reporting.

Obstacles to Progress

The following are specific obstacles to developing an efficient public health reporting system around this epidemic:

- Not all jurisdictions have made HIV test results reportable, as is the custom with laboratory reports regarding other conditions of public health concern.
- Underreporting and delayed reporting of data to local and state public health departments and from them to CDC are detrimental to surveillance efforts. These delays contribute to a public perception that information is deliberately being withheld by the federal and state governments.
- Not all practitioners and health care institutions fully understand their roles or procedures for the timely reporting of data or participation in surveillance efforts.
- Staff shortages and lack of ability to recruit quality staff inhibit the responsiveness of the various agencies.
- Funds are lacking to carry out surveillance programs in many areas of the country.

RECOMMENDATIONS

In response to the public health system obstacles, the Commission recommends the following:

1-8 Widespread, voluntary testing should be strongly encouraged at the federal, state, and local levels to improve the monitoring of incidence and prevalence, to enable those with HIV to protect themselves, and to help protect against the spread of the disease.

1-9 State public health departments should be fully supported in their role of coordinating the various federal programs and resources that are targeted for HIV, AIDS, and AIDS-related issues within their states.

1-10 All state health agencies not now doing so should move to require reporting and use this information to augment special studies to better understand HIV incidence and prevalence.

1-11 The Centers for Disease Control should accumulate HIV testing reports from all federal agencies conducting testing, without identifiers, for inclusion in national incidence and prevalence calculations.

1-12 The Department of Health and Human Services should explore a federal program to attract and recruit scientific and medical experts to serve as consultants and advisers to federal and state public health departments during a health crisis.

1-13 Where the data produced are needed for surveillance, programs of HIV testing sponsored by a state or local public health agency should be coordinated with the Centers for Disease Control and the methodology made consistent with the national effort.

1-14 State and local public health departments not eligible to participate in the specially designed prevalence studies conducted by the Centers for Disease Control should be given incentives to be involved in alternative data gathering activities.

1-15 All health care practitioners and institutions should be educated on procedures for reporting HIV infection and encouraged to provide requested HIV-related data in a timely manner, as required under public health reporting laws or requested in conjunction with special studies.

Section III. Data Analysis and Distribution

The results of data collection efforts are useful to many researchers attempting to study the epidemic and to public health officials and community-based groups trying to cope with its impact.

Obstacles to Progress

The Commission has identified the following obstacles to maximizing data analysis activities:

- Many users of AIDS and HIV surveillance data have no official forum to communicate their needs and recommendations to those who are responsible for compiling and disseminating the data.

- National data currently provided to community-based and ethnic or minority organizations, particularly Hispanic organizations, have been aggregated in a manner that is not useful for planning or response purposes.

- The development of data bases on HIV infection trends is important in addressing this epidemic. The scope of ongoing surveillance activities has not been able to encompass all groups and issues.

- Information regarding the rate of transmission of HIV in heterosexuals has not been forthcoming, and its lack has led to complacency and continuing high-risk behavior.

RECOMMENDATIONS

In response to obstacles in this area, the following recommendations are made:

1–16 Without delaying day-to-day responses to requests for data, the Centers for Disease Control (CDC) should establish a review group composed of representatives from state health organizations, the research community, community-based organizations, and members of the CDC staff, which can evaluate requests for data, review the methods of processing requests, and make recommendations on improving the provision and presentation of data pursuant to requests.

1–17 The Centers for Disease Control should break down data by sex, race, age, marital status, geographical location, and presumed mode of transmission, as well as combinations thereof, to the degree possible without potential compromise of identities. Age at diagnosis should be broken down into smaller groups so that researchers can better interpret the estimated age of infection from the date of diagnosis. The CDC should develop an improved method of identifying multiple risk factors present in any one case.

1–18 The Centers for Disease Control should oversee the collection and reporting of additional statistical data needed on specific groups, such as women, teenagers (10 to 13 years old and 14 to 19 years old), younger men (20 to 24 years old and 25 to 29 years old), intravenous drug users, and bisexual men and women.

1–19 The Centers for Disease Control should be responsible for quickly communicating to the research community the need for appropriate studies where statistical analysis is hampered by lack of other needed information, such as size of population subgroups (e.g., homosexual men, heterosexuals, sexually active teens).

1–20 Extensive research should be conducted and continually updated, and results should be widely disseminated to provide more accurate information on the spread of HIV into the heterosexual population.

1–21 The Secretary of Health and Human Services should coordinate data collected by the various entities involved with monitoring the HIV epidemic so that it is as compatible as possible, relating to Census Bureau geographic and demographic data and data from other standard sources, for comparative research purposes and to facilitate the appropriate targeting of prevention and care resources.

1–22 State and local public health agencies should make available local data directly to community-based organizations and other interested parties with regional or national needs in order to reduce the requests to the Centers for Disease Control.

Section IV. Mathematical Modeling and Analysis

Most epidemiological models are too simple to describe adequately a population as complex as that of the United States, and are based on classic epidemics (those with short, well defined periods when a person may transmit the disease and short, well defined periods of illness) which HIV is not.

There are a number of models that could be used to estimate prevalence of HIV infection. It is important to note that, while models are extremely useful in predicting the size and the shape of an epidemic, they are not designed to give precise information about the future.

Several models used by investigators to estimate the HIV-infected population are based on AIDS case surveillance data. This method of analyzing data is limited, however, by what is known about certain dynamics in the spread of the disease, transmission modes, behaviors and the natural history of the virus, as well as alternative combinations of the assumptions used.

Obstacles to Progress

The major obstacles to improving the predictive value of mathematical modeling are:

- Insufficient data.
- Insufficient models.

RECOMMENDATIONS

In response to these obstacles, the following recommendations are made:

1-23 The federal research agenda should include demographic studies necessary to better estimate the size of the various population groups in the United States.

1-24 The research being conducted on infectivity, the possible delay between infection and infectivity, the efficiency of HIV transmission, and progression from infection to death should be quickly communicated to those modeling the epidemic.

1-25 The public health system should expand the amount of available sentinel data from various high- and low-risk populations (e.g., hospital patients, penitentiary inmates, high school students, runaway youths, newborns) to improve the estimates of incidence and prevalence.

1-26 The research community should be actively engaged in developing innovative models that better describe and explain the transmission of HIV within the population.

CHAPTER TWO: PATIENT CARE

The health care needs of persons infected with HIV are varied and complex and present new difficulties for many segments of the currently overburdened United States health care delivery system. The Commission's examination of health care for persons with HIV-related illnesses has revealed several areas in urgent need of attention which, if given, will not only benefit HIV-infected persons, but will also promote better delivery of care to persons with other chronic illnesses.

Section I. The Patient Spectrum

Human Immunodeficiency Virus (HIV), the retrovirus which causes AIDS, is actually responsible for human infection with a wide range of consequences. In discussing and planning for appropriate patient care, it is critical to identify the range of patients who will need health care services. A complete patient spectrum starts with persons who are at risk for infection with HIV, ends with those who die of AIDS, and includes everyone in between. Patients enter the health care system at various points along the spectrum.

At the beginning of the spectrum are found the "worried well," those individuals who may have in the past or are currently participating in behaviors that put them at risk of acquiring HIV infection. Some of them may be infected but not yet symptomatic. They are all concerned about the possibility of infection and suffer from anxiety. The care of these patients includes diagnosis, counseling, education, and appropriate medical and psychological follow-up.

The Commission believes that doctors and all primary care providers should regularly incorporate HIV antibody testing and counseling as part of the normal range of medical services offered to well patients.

The Spectrum of HIV Infection: Stages of Disease

Recognition of the range of clinical manifestations associated with HIV prompted both the Centers for Disease Control (CDC) and the Walter Reed Army Institute of Research to develop HIV classification schemes in 1986. Classification divides HIV-infected persons into groups, which is useful for diagnosis, therapy, research, and public health planning and programming. The Walter Reed staging system includes immunologic criteria such as T4 cell count and cutaneous anergy (lack of detectable response to skin tests), as well as clinical assessment. (A chart and explanation of the Walter Reed system can be found in the Appendix.) The CDC system divides HIV into four mutually exclusive groups based on a presumptive chronology of infection and the presence of clinical findings. A single system may not be useful for all purposes.

As more information about the natural history of HIV infection is available and the range of disease manifestations become more fully understood, it may be possible to develop a classification system which could be used universally. In this section of the report, we will use the CDC classification scheme in discussing patient care and related issues, because the Walter Reed system requires more sophisticated assessment of the immune system through expensive blood tests which may not be available in all treatment settings. Complete descriptions of the range of HIV-related illnesses, pathogenesis, and the development and progression of signs and symptoms of disease have been expertly documented in the medical literature. The limited discussion presented here is for the purpose of defining who needs services, and what those services are.

CDC I

Often within three weeks of exposure to HIV, many people experience the symptoms of acute infection. Characterized by fever, lymphadenopathy (swollen lymph glands), fatigue, other mononucleosis-like symptoms, and less commonly aseptic meningitis or rash, this syndrome is usually self-limiting and often associated with seroconversion (the appearance of antibodies to HIV).

CDC II

Following the initial infection period and after seroconversion, most HIV-infected persons remain asymptomatic (without symptoms) for varying lengths of time. It is not yet known whether some of the persons in this category will remain symptom-free forever or whether with sufficient time all will go on to develop symptoms. Although, current data shows that approximately 35 percent of infected persons will develop AIDS within six years, some believe that with time it may approach 100 percent.

CDC III

A proportion of HIV-infected persons with no other symptoms do have a generalized lymphadenopathy which persists over time (often called PGL, persistent generalized lymphadenopathy).

CDC IV

HIV-infected persons with clinical symptoms can be divided into several groups based on the type and degree of symptoms experienced. Some infected persons suffer from constitutional symptoms, such as fever, weight loss, and diarrhea, which persist and are not associated with an identifiable cause other than HIV infection. This has been sometimes referred to as AIDS-Related Complex (ARC), but this terminology can be confusing. Because the term "ARC" is non-specific and tends to obscure the life-threatening aspects of this stage of illness, experts favor, and we concur, deemphasizing its use in favor of CDC IV-A and other classifications.

Other patients suffer from neurologic manifestations (CDC IV-B), which can include cognitive (thinking), affective (emotional), and sensory changes due to dementia, myelopathy (spinal cord disease), and peripheral neuropathies (nerve disease) without any concurrent illness to explain these symptoms other than HIV infection. Still other HIV-infected persons suffer from one or more of the classic opportunistic infections or malignancies that are diagnostic of AIDS. (CDC IV-C,D,E.) The commonly used term "persons with AIDS" (PWAs) is understood as encompassing any of the CDC IV subgroups. The Commission will refer to this group as "persons with symptomatic HIV infection."

Persons with HIV infection require a wide variety of care during the course of their illness -- in acute care hospitals, in outpatient clinics, in minimal care residential settings, in chronic care nursing homes and hospitals, in their homes, and in hospices. They meet many types of providers in the health care system during their illness: doctors, nurses, aides, and dentists; a wide variety of paramedical professionals; social workers; a spectrum of psychiatric workers; and workers and volunteers in community health programs who help them live at home for as long as possible. There is a shortage of these care givers today, and, as the HIV epidemic progresses, this shortage will become more acute.

It is important to stress that persons with HIV infection try to *live* with their disease. Approximately 10 percent of HIV-infected persons with symptoms diagnostic of AIDS do live for at least five years, and we are hopeful that life expectancy will increase as treatments improve.

Treatment Needs

Just as the spectrum of HIV infection and associated clinical manifestations covers a wide range, so do the treatment needs of persons at different points on the spectrum. Infected individuals at any stage should have access to a full range of quality services, including advice on nutrition and the spectrum of "wellness" programs. These services should be provided in a cost-effective and compassionate manner by adequately trained health care providers, and careful attention must be paid to continuity of care. Currently many obstacles prevent this from happening.

HIV-infected persons who are asymptomatic (CDC-II) need access to counseling and education services, regular follow-up by primary care providers, psychosocial services, and information about nutrition and other health behaviors that reduce the risk of secondary infection and prolong wellness and that help reduce their risk of spreading the infection to loved ones. Anticipatory planning and counseling about more advanced stages of the disease may also be helpful.

Although HIV infection is not curable at this time, many of its manifestations are treatable. Early diagnosis of both HIV and its clinical consequences results in more appropriate and effective care and management. A careful history, physical examination, and laboratory diagnosis are critical and should be regularly employed in diagnosing HIV infection and related diseases.

Early diagnosis of HIV infection can also assist the infected person to take precautions because of his or her suppressed immune system. The HIV-infected person must strive to avoid becoming infected with other diseases, both opportunistic infections and secondary infections, in order to lengthen life and enhance its quality. Definitive early diagnosis can assist in motivating the adoption of healthful behaviors.

HIV-infected persons with lymphadenopathy or constitutional symptoms (CDC III and IV-A) also have a need for counseling and education and for regular medical follow-up by a primary care provider who can manage the patient's symptoms. These patients need psychological support services, some need financial counseling and assistance, and linkage to other social services. The person with constitutional symptoms may need periodic hospitalization usually for diagnostic purposes or for symptom management, and in some cases may need support in the home to carry out activities of daily living.

Persons who, by virtue of clinical symptoms, fit into CDC IV- B, C, D are diagnosed as having AIDS and vary greatly in the type and degree of symptoms they exhibit. Persons with HIV infection need a broad range of health care services including diagnostic, prophylactic (preventive), and treatment services. Patients may have overlapping conditions, and treatment for one condition may worsen another. For example, chemotherapy for Kaposi's sarcoma may induce further suppression of the immune system. *Pneumocystis carinii* pneumonia may develop which, with aggressive and appropriate treatment, resolves over the course of a few weeks; Kaposi's sarcoma may exist with mild associated morbidity and no other symptoms for months or even years; chronic dementia, chronic candidiasis, chronic cytomegalovirus infection with sporadic episodes of more acute symptoms or infections all may occur singly or in combination. The appropriate health care delivery setting may vary from an intensive care unit to ambulatory outpatient care or care delivered in the home.

Two types of treatment interventions have significant potential to prolong and improve the quality of life of an HIV-infected person who is diagnosed early: prophylactic (preventative), such as the administration of drugs to prevent the onset of opportunistic infections; and curative, such as early treatment of *Pneumocystis carinii* pneumonia.

Treatment of Underlying HIV Infection

Persons at any stage of HIV infection or illness may wish to participate in experimental treatment protocols (clinical trials), and this opportunity should be available for as many as possible. Currently there is one antiviral drug, AZT (Zidovudine), approved for patients with AIDS after *Pneumocystis carinii* pneumonia or for HIV-infected persons with T4 cell counts lower than 200. There are many other drugs, including antivirals and immunomodulators, being used experimentally. AZT was shown to prolong life when tested in a multicenter, double blind trial. Some patients have suffered severe side effects prohibiting the continued use of AZT. Participation in an experimental treatment protocol requires health care services to administer the therapy, monitor tolerance and side effects, treat complications, and collect and analyze data.

Malignancies

Persons with HIV infection are more susceptible than the general population to a wide range of malignancies. Approximately one-third of AIDS patients die from cancer. The cancers that are most common are Kaposi's sarcoma and the lymphomas, both Hodgkin's disease, and the entire variety of lymphocytic malignancies. These are frequently referred to as "opportunistic cancers" because they occur more quickly and commonly in patients who have depressed immunologic host defense mechanisms. An underlying assumption is that these lymphomas and Kaposi's sarcoma may have a

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viral cause, and that the viral infection and subsequent cellular alteration to malignancy occurs more easily because lymphocyte function and host defenses have been damaged by the retrovirus that causes AIDS.

When one treats an AIDS patient who also has an underlying cancer, one walks a tightrope. Chemotherapy and radiation, both of which are effective cancer therapies, also attack the lymphocyte system. In a patient without AIDS, this is one of the major problems of cancer therapy, if not *the* major problem (i.e., giving optimal and maximal treatment of the cancer without obliterating the patient's immune system). In a patient with AIDS this problem is greatly magnified and becomes a more difficult problem as AIDS progresses. Thus, successful cancer therapy, producing a result that lasts for more than a few months, almost invariably occurs in a patient who has mild morbidity from AIDS, or mild morbidity from cancer, or both. Aggressive cancer treatment with advanced AIDS almost invariably produces short-lived results, and may eventually contribute to the patient's death.

It is important to remember that the clinical pattern of AIDS represents a wide spectrum of disease. When one superimposes upon the AIDS syndrome a broad spectrum of cancers, each one of which presents itself with a broad spectrum of activity from patient to patient, one can see that there can be no "standard" therapy, no "cookbook" solution, no easy therapeutic answer for the person with HIV infection who also gets cancer. For optimal management, most persons with HIV infection and cancer at one time or another have to be seen by specialists, in specialist services, in hospitals that have the required sophisticated staff, equipment, and laboratories to deal with their care. All of this clearly has both care system and financial implications.

Opportunistic Infections

Infections seen in AIDS parallel infections seen in other immunosuppressed patients, such as those with cancer. When people in the United States with normal immune systems die of infection, their deaths are caused by the usual spectrum of bacterial and viral diseases that have killed mankind for ages (i.e., infections with staphylococci, pneumococci, gram negative bacteria, and common viruses such as influenza, among others). Although as susceptible to these infections as any other person, immunosuppressed patients also suffer from infections -- "opportunistic infections" -- only rarely seen in people with normal host responses. They get critical and fatal infections from organisms that much of the normal population carries more or less with impunity, such as pneumocystis, toxoplasmosis and other parasites, cytomegalovirus, progressive systemic herpes and other viruses, cryptococcosis and other fungi, and unusual forms of tuberculosis that tend to be drug resistant. These are very difficult infections to treat, particularly in the immunosuppressed patient. They strike the patient suddenly and progress rapidly. Early and accurate therapy is essential, sometimes with drugs not immediately familiar or available to the general physician. This treatment usually has to be started by vein, and within hours of the recognition of infection. Thus, like cancer, these infections are best handled by specialists, in specialist settings or in hospitals where the proper staff is available with the appropriate equipment.

It should be added that the antibiotics used for these unusual infections are frequently very expensive and, as noted, not readily available. It is common for the person with symptomatic HIV infection to lack insurance or the funds to pay several hundred dollars a day for these drugs. Financial considerations are serious and are particularly critical for our hospital system, both public and private. The hospitals are rarely adequately reimbursed for this level of care, especially for indigents. Many voluntary hospitals attempt to divert these patients into the local municipal hospital system. This is becoming a fiscal challenge for our cities, where most of these patients are found.

Central Nervous System Manifestations

It is now clear that in addition to the various infectious and malignant manifestations of HIV in the central nervous system (CNS), there is a high prevalence of neurologic manifestations of HIV infection itself. The retrovirus causes cellular damage within the CNS. Although some have raised concern about the possibility of patients presenting with early cognitive changes associated with HIV infection, testimony presented to this Commission and recent scientific studies point to the observation that perceptible changes in mental activity usually occur in later stages of the disease. Further research on this point is being carried out. HIV infection in the CNS can result in vague symptoms, such as apathy and forgetfulness or can progress to full-blown dementia. Many providers of mental health or primary care may remain unaware of HIV infection as a possible organic etiology in the differential diagnosis of mental dysfunction. Because certain of the CNS problems associated with HIV infection, such as secondary infections of the brain, are treatable, attention to this feature of HIV infection is of increasing importance.

Psychosocial Needs

As in other fatal diseases, persons with HIV infection and their loved ones suffer high levels of distress, depression, and anxiety due to the great degree of uncertainty associated with the diagnosis. Often, there is an overwhelming task of sorting through changing medical and scientific information in order to make accurate decisions regarding health care and life planning. Much anxiety is created by the many questions about HIV infection which remain unanswered. In addition, many people with HIV infection and its various manifestations feel the need to hide their condition from friends, co-workers, employers, and even family members in order to prevent social isolation and ostracism. This contributes greatly to their psychological stress at a time when they are coping with a devastating illness.

Many people with HIV infection, especially those who are active intravenous drug users, are unemployed and without adequate financial resources. Other persons with HIV infection may lose their jobs because of discrimination or inability to work, also becoming financially needy. Some people with HIV infection are without homes or lose their homes. All of these factors contribute to the stress and anxiety experienced by someone who is seriously ill.

For the family of the person with HIV infection who is being cared for at home, there is considerable stress since at least one member of the family often must be available for full-time nursing care. A significant proportion of people with HIV infection do not have the support of family or close friends. For all of these reasons, the person with HIV and his supporting care givers require access to sensitive psychosocial support services. These include training in the bedside care of the patients, counseling, support groups, differential diagnosis, antidepressant medications, financial assistance, and social support services.

Special Populations

Certain groups of HIV-infected patients may have specific needs which differ from those of other population groups. For example, an HIV-infected woman of childbearing age has special needs for counseling about the morbidity and mortality risks to herself and a child she may conceive; a person who was infected as the result of a previous blood transfusion may exhibit a significant amount of anger requiring sensitive psychological services; children with HIV infection may have absent or ill parents creating unique needs for social and supportive services; homeless people with HIV infection need active assistance in finding a home in order to contend with this difficult illness. In another sense, a person with HIV infection and *Pneumocystis* pneumonia, for example, needs diagnostic services, acute treatment, nursing care, counseling, prophylaxis, follow-up, and supportive care whether that person is a hemophiliac, a homosexual, a drug user, black or Hispanic, a woman, a child, or a transfusion recipient.

All people with HIV infection have specific cultural and individual needs which must be respected and considered in the provision of health care. Health care providers should make every effort to elicit and respect patient preferences regarding care and treatment. Comprehensive health care services should be available and provided with compassion regardless of the patient's sex, age, ethnicity, financial status, or route of viral transmission. In addition, health care services, especially education, counseling and support, and respite care should be available to the families and loved ones of HIV-infected persons.

HIV-Infected Children

A population which poses unique challenges to the health care system are children with HIV infection. According to a report by the National Commission on Infant Mortality, by 1991, there will be an estimated 10,000 to 20,000 cases of symptomatic HIV infection in children in the United States. Most cases of AIDS in children (77 percent) are a result of perinatal transmission from infected mothers. These infants can be infected either through maternal blood *in utero*, by exposure to maternal blood and other body fluids during birth, or through breast milk.

In a newborn, a positive antibody test may indicate the presence of maternal antibodies, and the child is not necessarily HIV-infected. Maternal antibodies will disappear in 12 to 18 months, showing the child to be antibody negative and uninfected. Because HIV infection in asymptomatic newborns may not be diagnosed accurately for 10 to 18 months, all seropositive infants must be followed carefully for at least this length of time. Most infants with true HIV infection will be symptomatic very early in life.

Infants born with HIV infection are frequently the first member of their family to be diagnosed. An HIV-infected mother, usually a drug user or the sex partner of an HIV-infected individual, will transmit the virus to her newborn in 20 percent to 60 percent of pregnancies. Four to five percent of pregnant women in some inner city clinics are currently infected. As many as 4,000 babies will be born with HIV infection in the United States in 1988. Currently, one in every 61 babies born in New York City is seropositive at birth.

A special problem unique to many children with HIV infection is the unavailability of one or both parents due to AIDS or drug addiction, necessitating long-term or permanent hospitalization in the absence of any other available care setting. Infected mothers and newborns are typically from poor, drug-abusing, fragmented families. They rely heavily on Medicaid and on care and services provided by public hospitals and community agencies. HIV-infected babies, born to mothers who may be unable or unwilling to care for them, often live their brief, tragic lives in the ward of a hospital. Drug-addicted seropositive babies are also often born to mothers who had no prenatal care and they are often of low birth weight, frequently requiring prolonged hospital stays and possibly needing neonatal intensive care. HIV-infected babies can also be born with other sexually transmitted diseases, such as congenital syphilis.

Most of these children die of HIV-related diseases before the age of three. A few children have lived as long as nine years. The course of their illness is often stormy, with multiple and severe infections, presenting problems not usually seen on general pediatric wards. Because so many of these infants are born in the inner cities of New York, Newark, and Miami, those areas have seen the development of special pediatric units in hospitals serving their populations. The Commission has heard expert witnesses from each of these areas and made site visits to the specialized pediatric care delivery units of Harlem Hospital in New York and Jackson Memorial in Miami.

The care given the infants and children in these hospitals is exemplary and takes into account not only their medical needs, but their need to interact with other children and adults, develop normally educationally and socially, and be loved as any other child. However, as many pediatric care providers have testified, the hospital setting is less than optimal for long-term care for any child.

Pediatric patients require treatment for the broad spectrum of infections associated with HIV immunosuppression. Intravenous immune serum globulin given to symptomatic children has been shown to reduce recurrent bacterial infections in the study population. Clinical trials of AZT (Zidovudine) in children are currently ongoing. In addition, children require the whole range of acute, chronic, supportive, and terminal care services, specially tailored to the pediatric population. Health care providers who work with adults do not necessarily have the specific skills required to deal with newborns or children.

Experimental therapies for pediatric patients have lagged behind trials for adults due to the small number of patients available for study, and the cultural and ethical issues surrounding such treatment. Funds for additional pediatric trials are not currently available at NIH.

Thirteen percent of the children with HIV infection in the United States acquired the virus by means of transfusion, and six percent are hemophiliacs. These children are subject to the same range of secondary infections as perinatally exposed children, but are sometimes older, and therefore suffer the additional burden of having their otherwise normal lives severely altered by this new disease and the discrimination that often attends it. Parents of these children, while not necessarily indigent, may require financial assistance to care for their children, as costs can be catastrophic. Parents of all HIV-infected children may also have to deal with problems of their child's isolation or sense of abandonment, if relationships with friends and schoolmates change.

Adolescents and Teenagers

Though adolescents and teenagers comprise approximately one percent of all reported

AIDS cases, the degree to which this population is infected -- and infectious -- is clearly the more significant question. Prevalence data for adolescents are sketchy; however, preliminary data from a Baltimore study show that the prevalence of HIV infection in adolescents using Baltimore city health clinics is 1.5 to 2.0 percent. Data derived from the Department of Defense (DoD) screening of applicants for military service showed teen prevalence in some urban areas at greater than one in 400 (in the District of Columbia, the rate is one in 200). Limited DoD data indicate that the HIV prevalence rate is equal among female teen military applicants aged 17 to 19. However, data analyzed by gender and specific age show HIV prevalence rates in 17 year old female military applicants as twice that of 17 year old male applicants. Caution should be used in interpreting DoD data since teens seeking entrance to the military are not necessarily characteristic of the general population of teenagers.

The defining and publication of infection prevalence among teenagers is especially critical to prevention education in this age group because of the traditional tendency of teens to view their lives as permanent and because of the slow-acting nature of HIV, which causes symptoms to be rare in the teen population.

There are several important differences between adults and adolescents regarding HIV infection. Some of these are the following: a higher rate of heterosexual transmission; a higher percentage than adults of adolescents who are asymptomatic (who will become symptomatic in adulthood); a higher percentage of black and Hispanic AIDS cases; special legal and ethical issues around testing and provision of care to adolescents who are minors; and a lack of health services and programs that are appropriate to youths.

Adolescents are most likely to receive health care in their pediatrician's office, in school health clinics, and in STD and/or family planning clinics. When discussing a problem related to sexual behavior, especially homosexual behavior, adolescents are most likely to seek care from those service agencies offering confidentiality protection.

One ethical problem involves parental consent for testing and treatment. In many states where HIV is classified as a sexually transmitted disease, a minor may obtain testing and treatment without parental permission. This is not true of all states, and directly impacts on the delivery of care. In the absence of parental consent or knowledge a problem may result of having to reveal the diagnosis of an infection which is potentially fatal to a very young patient. Without the ability to also discuss his diagnosis with a parent or responsible family member, the physician is left to tell the child, and suggest appropriate counseling and medical follow-up. It is difficult if not impossible to give an adolescent a potentially fatal diagnosis without involving the parent or guardian in some way. Rarely, if ever, in our society, would a physician tell an adolescent that he or she has leukemia without also telling the parents.

Health care providers must be sensitive to the fact that HIV transmission in adolescents may occur through a range of situations and behaviors, including child sexual abuse, male homosexual or bisexual activity (which accounts for 50 percent of all diagnosed cases of AIDS in adolescents), and intravenous drug abuse.

Women with HIV Infection

With little exception, HIV research and programs have focused exclusively on homosexual men and intravenous drug users. As a result, there is limited information about the course of HIV infection in women. Diagnosis of AIDS in women may be late or less accurate because the natural history of infection in women is so poorly understood to date. There is some evidence to suggest that it differs from men. The problem of women with HIV infection is particularly important because it is directly linked to the rapid growth of the pediatric AIDS population.

The greatest number of AIDS cases among women occur in the black and Hispanic populations. Of all cases of AIDS in women, 51 percent are black, and 20 percent are Hispanic. The routes of viral transmission are the same for women as for men, but in women, HIV infection occurring directly from intravenous drug use, and through heterosexual contact with an infected man rank first and second, respectively.

One of the most serious problems facing the HIV-infected mother is the guilt she may feel after giving birth to an infected child, her despair as she watches that child die, or her anguish, knowing that after her own imminent death, she will leave children behind. Every member of the health care system providing service to HIV-infected mothers must recognize the desperation these women face and be prepared to encompass terminal care planning and child care considerations when delivering traditional health care.

Obstacles to health care access for poor women and their children may include lack of readily available clinics or physicians, inadequate transportation to the care setting, lack of child care arrangements while there, inability to obtain time off from a job if employed, and not least of all, some means to pay for care both for themselves and their children. More appropriate care providers and counselors are needed when dealing with minority women. For example, a black female patient may be more likely to seek treatment for a sexually transmitted disease or discuss sex-related problems if she could do so with a black female physician.

Hemophiliacs

Individuals with hemophilia (especially hemophilia A, a deficiency of Factor VIII) have been a group at very high risk of developing AIDS due to exposure to HIV through contaminated factor concentrate prior to heat treatment of Factor VIII. As of May 1988, CDC reported 597 cases of AIDS in adult hemophiliacs (plus 55 cases in children under 13 years old). According to the National Hemophilia Foundation, approximately 12,000 hemophiliacs have been infected with HIV, and five to 20 percent of their spouses are infected.

Men with hemophilia A are from many walks of life and geographic areas. They have lived dependent on medical care and the regular administration of factor VIII, the very substance which has turned out to be implicated in their infection with HIV. Approximately 75 percent of hemophiliacs are served by 214 federally funded regional Comprehensive Hemophiliac Diagnostic and Treatment Centers. These centers offer multi-disciplinary services including medical and preventive treatment, physical therapy, psychosocial support, dental services, and financial, vocational, and genetic counseling. Data compiled on the use of these centers have shown substantial savings by decreasing hospitalizations and clinic and emergency room visits.

Homosexual Men

When the health care provider approaches the homosexual or bisexual man who may or may not be HIV-infected, the concerns are much the same as with a heterosexual (i.e., the risks of exposure, number and identity of sexual partners, medical history/background, and information that may supply co-factor information). If it is established that the patient is infected, then the same problems of counseling about subsequent sexual activity, confidentiality of information, and contact notification emerge, but are compounded by fears of social isolation and provider attitudes towards homosexuality.

The health care provider must care for the homosexual man with awareness and sensitivity. A careful sexual, psychological, and family history must be obtained in an effective and non-judgmental manner. The provider should look for and evaluate Kaposi's sarcoma, which in HIV infection occurs almost exclusively in homosexual men. There should be a careful examination for bowel infections, bowel trauma, STDs, and other co-factors.

Some homosexual men experience societal and personal rejection, loneliness, guilt, self-hatred, and a loss of self-worth. Family abandonment is not uncommon. Meaningful relationships that exist with friends and the non-traditional family of the homosexual man must be recognized, so that these individuals may be included in care decisions if the patient so requests. Friction with relatives can occur and must be handled with care.

Heterosexual Adults

Although at present, the incidence of HIV infection is believed to be low in the general heterosexual population, there are distinct segments with much higher incidence of infection. Drug addicts and their sexual partners are at high risk and represent the principal mode of spread into the non-homosexual, non-intravenous drug-using population. Another risk is a history of prior blood transfusion. The risk of spread from bisexual men to their unsuspecting female partners is particularly worrisome because the magnitude of the risk is unknown. The estimated number of men who have had more than one casual homosexual experience, varies from 10 to 30 percent. An accurate assessment of this problem is currently lacking, but if 10 percent of the men in the United States are active bisexuals, this would represent the very distinct possibility of a large number of potentially HIV-infected women, many of whom have no knowledge at all about their sexual partner's homosexual activity. Almost by definition, the homosexual lives of bisexuals, especially those who are married, are clandestine, with transient, and possibly anonymous contacts, thereby exposing them to greater risk of HIV infection.

As is true for all sexually transmitted diseases, an increased number of partners represents increased risk and any person with multiple partners must be advised to reduce the number of sexual partners. Any health care provider must underline to everyone he or she counsels that the "window" between infection and a positive antibody test, although usually between six weeks and three months, may be as long as three years or more, and therefore an initial negative test may be misleading. (Testing methods currently under development are expected to greatly reduce this problem.) For freedom from exposure to HIV, long-term mutual monogamy remains the best prevention short of abstinence.

Because the epidemic has predominantly been confined to people participating in behaviors such as homosexual sex and intravenous drug abuse, health care practitioners are less likely to consider a diagnosis of HIV positivity or AIDS in an individual apparently not at high risk, such as a white heterosexual non-intravenous drug-using female who is not aware that her sole male partner is infected. In the past, this situation has extended the length of time from onset of symptoms to diagnosis of such individuals. One compelling witness before the Commission revealed that she had gone to doctors for nearly two years with mild to severe problems before anyone thought to do an antibody test. Because no one associated her with high-risk behaviors, no one suspected that she might be HIV-infected. She now has AIDS.

Minorities

The Task Force on Black and Minority Health (1985) for the Secretary of Health and Human Services described the problem of minority access to health care and documented a wide range of inadequacies in the provision of health information and health care to blacks, Hispanics, Asians, and Native Americans. These groups were repeatedly the least likely to be the target of health education or service programs even though their health condition suggests their needs are great.

The impact of HIV infection on black and Hispanic communities has been felt very strongly; individuals from these groups comprise about 40 percent of all persons with symptomatic HIV infection. Similar to the non-Hispanic white population, the major category of transmission for blacks and Hispanics is homosexual/bisexual behavior. However, blacks and Hispanics who engage in these behaviors are less likely to obtain services from organizations which are perceived as homosexually-related and more likely to seek information and guidance from those community-based organizations which have traditionally served their respective communities. Of great concern is that intravenous drug use is a much greater method of transmission for blacks and Hispanics than it is for non-Hispanic whites. The incidence of HIV infection among inner city drug users is growing more rapidly than the incidence in the homosexual population. Most of these patients have no private health insurance and must rely on Medicaid. It is only recently that black and Hispanic community-based organizations have been able to obtain funds so that they could also use their diverse expertise and credibility to address the HIV epidemic. Openly homosexual support groups encourage early diagnosis, treatment, and education in their respective communities. Homosexual support groups are only now emerging in a few black and Hispanic communities, and can make significant contributions. Leadership is critically needed from major national minority organizations and from churches in minority communities.

Overall, the provision of health care services to blacks and Hispanics has been hampered by the large number of uninsured persons, i.e., persons with neither public nor private health insurance, including significant numbers who are employed. Moreover, the great variability in Medicaid coverage by states creates totally different service pictures in states such as Texas, Florida, Mississippi, and Alabama as compared to New York or California.

Large numbers of minorities are uninsured or underinsured and, consequently, turn to public health care systems, creating high levels of demand for services from public clinics and hospitals, community health centers, and migrant health centers. The demand is also felt by the National Health Service Corps, which provides, in part, personnel for public facilities. Ensuring the ability of public facilities to provide care and treatment to black, Hispanic, and other poor HIV-infected persons is difficult in the absence of significantly higher levels of funding. The goal of such funding is not only to provide the best possible AIDS services but also to continue the unfinished job of expanding minority and indigent access to health care.

The other major public system, the Indian Health Service, must also be brought fully into the battle against HIV. Despite the fact that the incidence and prevalence among Native Americans remain relatively low, the opportunities for primary prevention and early intervention should not be lost. The prevalence of HIV infection in this population is not well documented, but anecdotal reports make it clear that both reservation and urban residents are reporting positive test results and are in need of services. Currently, the incidence of AIDS among Asian/Pacific Islanders is not high. However, with large numbers of these individuals residing in high-incidence areas, the likelihood of increasing levels of HIV-related health problems cannot be discounted. As in the case of blacks, Hispanics, and Native Americans, traditional problems of access to care must be considered and overcome.

The much needed attention to low-income and uninsured blacks and Hispanics should not obscure the fact that many in these two minority populations seek health care services from private physicians. Thus strategies for assuring appropriate high-quality care and treatment must look also to the private sector. Unfortunately, blacks and Hispanics are underrepresented in the health care professions -- as are Native Americans and Asian/Pacific Islanders. The lack of such personnel has long been recognized as a barrier to health care. While the response to HIV should add impetus to the recruitment and training of minority providers, interim solutions are demanded as well. HIV-related training can be focused on providers in predominantly minority communities. Because non-minority providers play a significant role in many of these communities, there is a need to extend such education and training beyond AIDS-specific protocols to matters of values, culture, and language in order to improve utilization and provider/patient relationships and patient outcomes. Further, the role of the family as caretakers and survivors cannot be sufficiently emphasized, and training must be made available to families of infected persons. Minority providers, already knowledgeable and having the trust and support of their communities, should be viewed as a resource to contribute to this larger educational effort.

In the course of the epidemic, many myths about blacks and Hispanics have developed. It has been said that families will not provide support and care for patients. Lack of motivation to participate in clinical trials has been suggested. Those working with the populations know otherwise. These populations have suffered as a result of such myths, but an even more serious problem is the isolation from the message of hope -- the growing availability of experimental treatments and the importance of early diagnosis and care. Black and Hispanic populations must be reoriented to this perspective, and the systems must be in place to aggressively and effectively respond.

Drug Abusers

Patient care for active drug abusers is principally complicated by the non-compliance and unreliability of this patient group. There is no certainty that medications are taken, and follow-up is frequently poor. There are usually many other conditions present which make their prognosis particularly poor (e.g., other venereal diseases, poor general health, damaged immune systems independent of HIV infection, and unstable and frequently violent lifestyles). Treatment settings are often emergency rooms, and opportunities for long-term care intervention are limited. In this context, treatment may be less than aggressive or complete, contributing to shorter survival. HIV intervention, diagnosis, and counseling for drug abusers should be incorporated into drug treatment centers.

Section II. The Health Care Delivery System

Health care in the United States is delivered through hospitals (public and private), outpatient clinics and doctors' offices, home care agencies, nursing services, long-term care facilities, hospices, counseling services, social and psychological support services, and community-based organizations. Services available vary widely from community to community. To date, the HIV epidemic has had an uneven impact on the United States health care delivery system. In low prevalence areas, the care system has been much less challenged than high prevalence areas such as New York, California, or New Jersey. As a result, most of the country has not yet experienced the extraordinary demands on health care delivery systems as are now being experienced in these states. As the epidemic continues, however, more areas should anticipate a measurable impact.

The HIV epidemic is placing an increasing strain on segments of our health care system, particularly our municipal and voluntary hospitals. This strain is illuminating many of the flaws in our health care system that have been present for a long time. As we try to address these flaws and the variety of possible solutions, we hopefully will end up with a better system which will be more responsive, more humane, and more able to direct its manifest strengths quickly and efficiently to where they are most needed.

Inpatient Hospitalization

To date, hospitals are the primary providers of care for persons with symptomatic HIV infection through inpatient hospital admissions. A number of acute care hospitals in the United States, including San Francisco General, St. Clare's and St. Vincent's Hospitals in New York, Johns Hopkins in Baltimore and others have developed discrete, dedicated inpatient and outpatient units as the core of their AIDS program, and serve as models for care. Persons advocating these structures assert that quality patient care can be provided in a more efficient and effective manner when delivered by a multi-disciplinary team of health care providers dedicated to the care of persons with symptomatic HIV infection. St. Clare's AIDS unit, for example, provides complete dental services.

In many areas, specialized AIDS health care teams or units do not exist and persons with symptomatic HIV infection are placed on general medical/surgical units of hospitals (so called "scattered placement") and cared for by a variety of practitioners with differing levels of experience in caring for persons with HIV infection. This is especially true in low-incidence areas.

The costs of caring for persons with HIV infection are extremely high. Estimates from recent studies calculate the AIDS-related hospital bill for 1985 at $380 million, and economists project costs greater than $8.5 billion for AIDS-related medical care by 1991. Financing of care is complex, coming primarily from private insurance, Medicaid, and other state, local, and private monies. Increasingly, the cost burden of providing care to persons with symptomatic HIV infection is falling to the public hospitals, the state and local public assistance programs, and Medicaid.

Comprehensive Services

Witnesses before the Commission, in agreement with most experts in this field, noted the importance of establishing comprehensive and coordinated service delivery systems for people affected by the spectrum of HIV infection in order to reduce both service fragmentation and cost. San Francisco, largely through the intensive efforts of its homosexual community, developed an integrated community-based system of comprehensive services for people with HIV infection. This case management model was centrally coordinated primarily through San Francisco General Hospital, and was developed at a time when the city was in a budget surplus, and experimentation with new and innovative care approaches was possible. Outpatient support services were provided through the Shanti Project and other organizations supported in part by the San Francisco AIDS Foundation. Efforts were made to ensure that a patient transferred from one care setting to another did not get "lost in the system" but experienced care managed with continuity. The result was comprehensive and well delivered care, delivered in the treatment setting of the patient's choice, and costing less than inpatient care. Several other communities are currently developing similar service networks emulating the San Francisco model.

Currently there are 22 AIDS Service Delivery Demonstration projects being conducted in the United States. These projects are being funded by the United States Public Health Service, Health Resources and Services Administration (13 projects), and by the Robert Wood Johnson Foundation (nine projects). These projects are attempting to develop and demonstrate an effective comprehensive model or network of out-of-hospital community-based care for people with HIV infection. This model is to be coordinated, efficient, cost-effective, and humane. Recognizing the specific needs and existing resources of its own community or region, each program has, or is developing, a coordinated network of services, including:

- outpatient care (diagnostic, treatment, follow-up, and psychosocial care services);
- in-home care (such as high-tech home therapies, hospice care, homemaker and attendant care);
- long-term care not in the home; and

- patient care services, including services provided by Visiting Nurses Services, and many other home health care organizations.

Each project includes linkages with acute care hospital facilities which provide care to people with HIV infection, and some projects include services to children. To assure continuity, a case management model is utilized in each project. Evaluation of these projects will allow the development of service delivery models which will be available for replication by other communities and regions.

Out-of-Hospital Care

In addition to the work of the San Francisco community, the Commission recognizes the tireless efforts of many religious and community-based organizations nationwide in providing compassionate care for persons with HIV infection, particularly for those who are most indigent. The availability of care settings staffed by practitioners knowledgeable in the care of HIV-infected persons is an essential alternative to hospital-based care. There is a vital need for replicating the coordinated system developed in San Francisco, and for reimbursement systems to respond by supporting high quality and cost-effective care in out-of-hospital settings.

Home care should be made available, particularly for the indigent, covering the range from high-tech intravenous therapies to chronic care by attendants. The average cost of home health care is $15,000 per year, while the average year cost for nursing homes ranges from $24,000 to $60,000, depending on geographic location. Hospice care should be available, as well as nursing home beds or residential facilities for those who cannot be adequately cared for in their homes. Currently, there are few nursing homes that will accept patients with advanced HIV illness; this situation must be resolved, and additional alternative settings sought. In some areas, small group homes and nursing services may be a feasible approach. Reimbursement and funding for these services should be available from a variety of sources. Homeless persons with AIDS often remain in the hospital because they have no home address to which they can be discharged. Nowhere is this more evident than with the hospitalized infants and children with HIV infection, the so-called "boarder babies." The cost of maintaining a child in a municipal hospital pediatric ward for one year is in excess of $250,000. Congregate living facilities have been identified as a potential alternative to hospital-based care, and are often able to provide a quality home environment for $60 to $100 per day, versus $500 to $1,000 per hospital day. Some private sector institutions have begun to provide high quality, cost-effective, and compassionate care for homeless persons with AIDS and their families. Notable models among these include Bailey House, a unique public-private partnership between New York City and a public foundation, the hospices run by Mother Teresa, and many other local efforts by religious organizations.

Community-based organizations (CBOs) have played an enormous role in providing health care and psychosocial services for persons with HIV infection. The prototypes for these organizations were developed within homosexual communities nationwide and illustrate, through their diversity and numbers, a self-reliant and vigorous response in coping with the HIV epidemic. CBOs often provide services not otherwise available through the health care delivery system. They are not-for-profit, indigenous to the locale, and rely heavily on volunteers. Many CBOs serve a large percentage of poverty level income, minority, and other underserved clients.

Obstacles to Progress

The Commission has identified the following obstacles to progress in health care delivery to persons infected with HIV:

- Witnesses before the Commission and other experts expressed concern that our health care delivery system currently is structurally and financially unprepared to deal with the diverse needs of people with HIV infection, as well as those with other chronic illnesses.

- Much of the newly emerging HIV patient population is dependent on already overburdened municipal hospital systems.

- In many areas of the country, services and specialists are not adequately available to individuals in need, especially to those who are HIV-infected but who do not experience the symptoms of AIDS.

- Currently, the vast array of services required for people with HIV infection are uncoordinated or may be available only in pieces. A person with HIV infection is confronted by a complex system of fragmented and expensive services. Out-of-hospital care is generally inadequate. Indeed, a large and growing number of HIV-infected persons are poor and medically underserved, are covered by Medicaid and other forms of public assistance. If a wider range of coordinated out-of-hospital services were available, hospitalizations could presumably be decreased.

- The range of services is inadequate to meet the diverse and often complex needs of HIV-infected families, including mothers and children. Available services, such as day care, home care, respite care, and psychosocial services, would decrease the number of hospitalizations of children with AIDS, possibly improve their quality of life, and help maintain the intactness of the natural family.
- Although hemophilia treatment centers are models of comprehensive care for hemophiliacs, there are unique needs of HIV-infected hemophiliacs and their families for which these centers are not adequately funded or prepared.
- In many areas, zoning restrictions prevent use of facilities which might otherwise provide a site for cost-effective care to persons with AIDS.
- Minority and indigent populations often have no access to health care and/or are often medically underserved.
- The range of health care needs for HIV-infected persons is complex, and infected individuals often do not have a primary health care provider to provide appropriate medical care selection or follow-up.
- Health care service resources to date have primarily been directed toward meeting the acute care needs of persons diagnosed with AIDS and have not been available to others in the HIV patient spectrum for diagnosis, early intervention, or support.
- Psychosocial services are frequently unavailable to persons needing this type of care.
- Care settings are inadequately used as points of intervention to test and counsel patients about modes of transmission and behavior modification.
- Support and assistance with activities of daily living is generally not available to ill persons except on a limited basis by volunteers.
- Much remains to be learned about the most effective and efficient way to manage the care and associated needs of HIV-infected persons without compromising the availability or quality of the care they receive.

RECOMMENDATIONS

In addressing these obstacles to progress in making the needed services available to HIV-infected persons, the Commission recommends the following:

2-1 All members of the health care provider community should treat patients with HIV infection with professionalism, and every effort should be made to maintain an individual's autonomy, sense of self-worth, and personal dignity.

2-2 Health care facilities should provide or arrange for a case manager or some equivalent mechanism for assuring continuity of care for HIV-infected persons who use their facilities.

2-3 All physicians and primary care providers should regularly utilize the HIV antibody test as a diagnostic tool, and incorporate the test and counseling into the normal range of services offered to patients.

2-4 The Community Health Center Program should be increased in high incidence areas to allow for the provision of additional services to persons infected with HIV. The federal allocation would provide primary medical and dental care for patients and would also allow for the training of current and new staff.

2-5 The federal government, through the Department of Health and Human Services, and the states should provide funds for home health care services for underinsured persons with HIV infection. Each state's federal allocation for home health care would be based on the ratio of the number of persons with HIV infection in the state to the total number of persons with HIV infection in the United States. States should have the option to utilize this allocation for grants to home health care agencies for the provision of care to eligible individuals, for compensation for the planners and providers of care, and for education and training of home health care providers.

2-6 Facilities which currently care for persons infected with HIV should be encouraged to make available psychosocial care as needed, within the limitations of each facility's resources. Care may be provided by psychiatrists, psychologists, psychiatric nurses, social workers, marriage counselors, sex counselors and therapists, family counselors, or religious counselors, as appropriate. All providers of psychosocial services should be enlisted in efforts to prevent HIV transmission.

2-7 Federally funded community mental health centers should develop programs targeted for persons infected with HIV and their loved ones. To ensure the availability of these services, the Alcohol, Drug Abuse, and Mental Health Services Block Grant funding should be increased.

2-8 The Health Resources and Services Administration should evaluate health care provider attrition from municipal hospitals in high prevalence cities, to determine means by which incentives can be developed to retain nurses, physicians, and other direct health care providers.

2-9
10-10 The Health Resources and Services Administration, through the Maternal and Child Health Program, should provide funding for demonstration grants for Regional HIV Comprehensive Family Care Centers in areas where inadequate pediatric services exist and the prevalence of HIV infection is high. These centers would provide a full range of services to HIV-infected children, adolescents, and their families including: diagnostic, treatment, and follow-up services, prenatal and well-baby care, testing, counseling, psychosocial support services, day care, respite care, education, and linkages with home care and acute hospital care.

2-10 Where pediatric infection rates are high, based on pediatric seroprevalence information, obstetricians and pediatricians should counsel patients and advise testing as appropriate.

2-11
10-11 The Health Resources and Services Administration (HRSA) should widely disseminate findings from the AIDS Service Demonstration Projects so that other communities can select and develop the most appropriate and feasible model. The Public Health Service through HRSA and in collaboration with the states should provide initial funding and technical assistance to communities in order to establish services to fill existing gaps and to develop coordinated networks of service. Systems created should include a continuum of services, emphasize alternatives to hospitalization, and utilize a case-management approach.

2-12 The National Center for Health Services Research should compile data from hospitals using dedicated AIDS units and those using scattered placement in order to compare their effectiveness with respect to quality of care, patient satisfaction, and the effect on staff (i.e., on recruitment, retention, turnover rate, and satisfaction). Findings should be disseminated to hospitals nationwide to help them plan and design the most appropriate structure for service delivery to people with HIV infection.

2-13 In areas where availability of intermittent or chronic care services is encumbered by local restrictions or zoning requirements, such as number of exits required for a building or allowable number of occupants of a facility, local governments should provide reasonable variances to permit such care to be available.

2-14 Current funding to the Comprehensive Hemophiliac Diagnostic and Treatment Centers should be increased to cover the costs of HIV testing, counseling, evaluation of immune system function, and supportive services for the patient and family. Funding of immune system evaluation will enhance the use of the Centers for clinical research.

2-15 The Department of Health and Human Services should take steps to ensure that all Comprehensive Hemophiliac Diagnostic and Treatment Centers are fully prepared to offer HIV-related care to any patients, and to extend the network of centers to the remaining 25 percent of the hemophiliac population not now being served.

2-16 Municipal hospital systems in high prevalence cities should assess their current and five-year anticipated demand for HIV-related services and forward these projections to the Secretaries of the United States Departments of Health and Human Services and Housing and Urban Development for incorporation into a plan for increased funding for patient care in community and long-term care settings.

2-17 The Department of Health and Human Services should make the development of new strategies for diagnosing, educating, and caring for adolescents at risk for HIV infection a high priority.

2-18 The Pediatric AIDS Health Care Demonstration Projects grants announced by the Health Resources and Services Administration should be funded through 1991. Grants should be awarded to programs which are family-focused and community-based, include a coordinated, comprehensive network of services, and should utilize a family case management approach.

CHAPTER THREE: HEALTH CARE PROVIDERS

Health care in the various settings previously described is provided by an array of professional and non-professional care givers. These include: physicians, both generalists and specialists; nurses and auxiliary nursing personnel; dentists; social workers; psychologists and other mental health workers; volunteers; emergency care providers and other "first responders," including fire fighters and police. Adequate numbers of appropriately skilled and prepared providers are essential to the provision of needed services for persons with HIV infection.

A well-educated, skilled, and concerned health care community is not only vital to the task of caring for those who are ill, but during this critical time when fear and misunderstanding about the HIV epidemic exist within our population, the leadership established by providers of health care to persons with HIV infection is crucial to fostering a sense of compassion and rationality among all our citizens. When health care professionals care for all patients who need their help, regardless of HIV infection status, and do so without reservation or trepidation using time-tested infection control methods, they communicate to all people that calmness and reason can prevail over panic and anxiety as we confront this epidemic.

There is clearly a need for more knowledge about HIV among many health care providers -- an issue that was repeatedly raised by expert witnesses at the hearings on care. An assessment is currently underway to collect comprehensive data from medical college accreditation bodies and elsewhere, on how health professions schools have adapted their curricula to assure that students are being prepared to diagnose and treat or prevent HIV-related illness. There is a need for an effective, coordinated response within the health care community to promote adequate education for every provider about modes of transmission, prevention, recognition, and management of HIV infection.

Section I. Developing a Broader Provider Base

Physicians, Dentists, and Paramedical Professionals

Some of the issues that have been presented in testimony regarding health care providers are:

- that the health care system has been faced with a sudden increased demand for certain HIV-related medical specialties, e.g., infectious disease specialists, immunologists, and dermatologists. Currently, these specialties are underenrolled in many medical schools.
- that there is still considerable anxiety on the part of some health care workers about risk of workplace exposure, and that there is a migration away from those health care settings and practices that may include risk.
- that with the evolution of the case management model many of the patient care decisions have been appropriately vested with nurses at a time when the country is facing a severe shortage of nurses.

Obstacles to Progress

- The acuity of disease of persons with HIV infection, the complexity of their physical and psychosocial needs, the high fatality rate, and the fear of exposure to HIV, along with low salaries and understaffing in many facilities, create a potential for considerable stress, burn-out, turnover, and dramatic projected shortages for the delivery of HIV patient care in the near future.

- There is underenrollment in many of the physician specialties associated with HIV treatment, and future shortages are projected.

- In many cities and counties, whether formally identified as health manpower shortage areas or not, the full continuum of health services required for the intensive treatment of symptomatic HIV-infected patients is unavailable.

- As the number of HIV cases increases, finding adequate numbers of physicians, dentists, and other primary care personnel in high prevalence areas, where recruitment of physicians is already difficult, will be a serious problem.

- Complete and up-to-date information about HIV is not readily accessible to front-line providers, persons with HIV, or the general public except through certain limited commercial enterprises or medical libraries at academic institutions. The attempts to create centrally coordinated access have not been successful.

- Minorities are severely underrepresented in the health professions.

- The professional medical education system has not moved synchronously with the HIV epidemic. As a result, there are significant gaps in knowledge among many providers about management of this illness.

- There are currently no comprehensive data, within medical college accreditation bodies or elsewhere, on how health professions schools have adapted their curricula to assure that students are being prepared to treat or prevent HIV-related illness.

- The average age of both nursing and medical students is rising; a large number of the students already face adult responsibilities. The way in which financial scholarship need is calculated can penalize adult learners by disallowing deductions for adult financial obligations such as dependents and home mortgages -- thereby limiting the student's ability to obtain grants or loans.

- Education for graduate physicians in specialty training and continuing education for practicing physicians may or may not address HIV prevention and treatment. As a result, many physicians are severely lacking in knowledge about HIV.

- Dental professional education, according to dentists themselves, has been lacking in providing education about management of persons infected with HIV. This has contributed to limiting access to dental care for persons with HIV.

- Pre-hospital emergency care providers (paramedics, firefighters, and police) have an immediate and continuing need for more education about infection control, because their frequent exposure to blood and body fluids in their handling of all types of persons in uncontrolled settings places them at increased risk of exposure to the virus.

- Providers of allied health care (including social workers, therapists, aides, laboratory personnel, and many others) are also in need of more complete education about HIV because their educational background may not have provided sufficient information about infection control and other aspects of providing care to persons with HIV infection.

- Availability of trained personnel qualified to provide psychosocial services for persons infected with HIV or their loved ones varies across the country. In many areas, an insufficient number of staff are available to respond to current needs, and this shortage will deepen as the number of persons with HIV increases.

- The psychological burden on health care providers who care for persons with HIV is severe, and many providers may leave the profession if they have difficulty coping with these stresses. They may also face suspicion or intolerance from members of the general public who may fear that the providers themselves have become infected through their work.

RECOMMENDATIONS

In addressing these obstacles to progress in preparing adequate numbers of health care providers for the care of HIV-infected persons, the Commission recommends the following:

3-1 The Department of Health and Human Services should administer a competitive grant or contract program, or organize consensus conferences, to construct HIV treatment guidelines for practitioners in differing practice environments encompassing a range of medical specialties and including other disciplines. The guidelines developed should then be made available to all practitioners who request them.

3-2 Health care professions schools should assure that all students are educated about HIV infection and those related subjects most needed in providing care to HIV-infected patients and their families, including: death and dying, pain control, palliative care, human sexuality, substance abuse counseling, ethics, and infection control.

3-3 Health care professions schools should be given incentives to recruit medical students into specialties that are underrepresented but needed due to the HIV epidemic.

3–4 Eligibility for financial scholarships and grants should include evaluation mechanisms that take into account the adult financial responsibilities of adult students.

3–5 The Health Resources and Services Administration should develop a model program to create innovative techniques to recruit, train, and retain nonprofessional health care providers.

3–6 The federal government, through the National Institute of Mental Health, should continue to provide funding for development of psychosocial and neuropsychiatric provider education and training programs to ensure continued availability to those who need such care in the future.

3–7 Institutions which employ health care providers serving persons infected with HIV should provide psychosocial support to their staff on a proactive and continuing basis.

Nursing

The role of nursing in providing care to people with HIV infection cannot be addressed without acknowledging a deepening shortage of nurses in the workforce. In addition, the stresses associated with providing care for chronically ill patients in need of long-term and terminal care, combined with a potential, albeit small, risk of exposure to infectious agents may be negatively influencing the choice of nursing as a career for some people.

Nurses have a foundation of biophysical and psychosocial knowledge which enables them to provide quality care to HIV-infected persons in a safe and effective manner. This knowledge enables nurses to function in the role of case manager at its fullest potential. Nurses are educated to provide for the physical, psychological, emotional, social, and spiritual needs of their clients. Nurses have the responsibility, as do all health care professionals, to equip themselves with accurate information about HIV and the care of HIV-infected persons.

Nurses are currently providing care in a variety of health care settings such as hospitals, clinics, home care, hospices, nursing homes, schools, occupational sites, and others. However, in the hospital setting alone, the vacancy rates for registered nurses exceed 13 percent. Recommendations to ensure an adequate supply of appropriately prepared nurses for care of the HIV-infected patient will be made in this report within the context of a general nursing shortage. The issues of salary compression (the narrow range of salaries in which nurses top out early in their careers) and restrictions of full use of judgment are major causes of nurses leaving the field for other careers. Planning must also include strategies for retaining nurses already in the workforce.

The professional nurse educated at the BSN (Bachelor of Science in Nursing) level and above is educated to care for patients and their families in a variety of complex settings, both in the hospital and in the community. This professional nurse is educated additionally in disease prevention and health promotion for a variety of patients and their families in the hospital and in the community. In contrast, the technical nurse is educated to care for such patients in hospitals who have well-defined patient care problems.

The demand exceeds the supply of highly educated nurses to manage the sophisticated health care needs of tomorrow. The projected supply of BSN nurses for the year 2000 is 596,000 full-time equivalents, while the need is set at 853,800. The supply of masters and doctorally prepared nurses is projected to be 174,900 while the requirement is projected to be 377,100. The most acute shortage in nursing generally -- that of nurses with higher education -- is made more acute by the intensive training needed to care for patients affected by HIV. The number of nurses trained to the associate degree or diploma level is projected to be more than adequate for the nursing positions which can be filled by those at these lower educational levels. However, considerable testimony has indicated that some inner city hospitals are facing a shortage at this level, too, primarily due to low hourly wages at municipal institutions.

Obstacles to Progress

- The demand exceeds the supply of highly educated nurses to manage the sophisticated health care needs of tomorrow.
- Preliminary projections by the Department of Health and Human Services for the year 2000 indicate the need for 38 percent more nurses than were required in 1985. Simultaneously, enrollment in schools of nursing continues to decline, necessitating clear, deliberate action on the part

of the health care industry and the state and federal governments to promote the profession of nursing.

- The level of compensation provided to nurses is markedly lower than necessary to attract and retain adequate numbers of individuals to the field. Differing levels of education, skills, and expertise, as well as the personal sacrifice requisite in a nursing career are reportedly rewarded inadequately at current compensation levels.

- Federal funding for nursing training and education has remained constant and, in fact, decreased in some programs over the last several years, rather than being increased to meet the increased need.

- The traditional mechanisms available for students to finance nursing education consist of a patchwork combination of scholarships, loans, workstudy programs, work payback programs, and traineeships. Sources of these funds for LPN (licensed practical nurse), Diploma, AD (Associate Degree), BSN (Bachelor of Science in Nursing), MSN (Master of Science in Nursing), and doctoral nursing students have been cut or lost.

- As with medical students, the average age of nursing students is rising, creating a large number of non-traditional students with adult responsibilities. Current methods of calculating financial need can penalize adult learners by disallowing deductions for adult financial obligations.

- The nursing profession also has need for more education about HIV. While curriculum changes relating to HIV educational programs at American colleges of nursing have been considered, and while there have been several initiatives to educate practicing nurses, the response is still inadequate to meet current and projected needs for more education.

- Traineeship funds from the United States Public Health Service's Division of Nursing are available only to RNs who seek to continue their professional education by pursuing a higher degree. Non-RNs pursuing nursing as their first professional degree are not currently eligible for traineeships.

- The nursing care of persons with HIV infection is complex and intensive, and consumes a disproportionate amount of nursing time and hospital resources.

RECOMMENDATIONS

3-8 The Public Health Service's Division of Nursing should fund demonstration projects to evaluate models of nurse-managed care for persons with HIV infection or other chronic illnesses. Included should be an evaluation of the Community Nursing Organization concept (as described in the Community Nursing and Ambulatory Care Act of 1987) applied to the care of HIV-infected persons. In addition, models of differentiated nursing practice, employing nurses in differing job descriptions based on varying levels of education, should be evaluated.

3-9 The Public Health Service's Division of Nursing should alleviate restrictions for nurse traineeships and provide funding for stipends for full-time and part-time nursing students. Traineeships should be available for RNs pursuing higher degrees as well as for those students who are not yet registered nurses but are pursuing nursing higher education. Special emphasis should be given to nurses pursuing advanced degrees in community health nursing, school health nursing, and occupational nursing.

3-10 The National Institute of Mental Health should reinstate funding for traineeships to educate psych-mental health nurses at the masters and doctoral levels who will be needed for counseling efforts.

3-11 Funding for the current Nursing Student Loan Program should be increased, and eligibility requirements for low interest loans should be modified.

3-12 Nursing work payback programs should be established by the federal government to provide tuition support for education and living expenses. Such programs would have a greater forgiveness clause for students working in facilities which provide care to persons who are infected with HIV, including hospitals, long-term care facilities, community-based organizations, drug treatment facilities, and others that meet the expanded definitions of medically underserved areas.

3-13 Hospitals, other employers of nurses, and schools of nursing should be encouraged, in conjunction with the federal government, to provide both financial and scheduling incentives for nurses to pursue advanced degrees in nursing.

3-14 Nursing organizations in conjunction with the Division of Nursing in the Health Resources and Services Administration should establish guidelines for health care institutions for the implementation of counseling and support services for nurses caring for HIV-infected persons with appropriate mechanisms for assuring their implementation.

3-15 Additional funding should be provided through the Public Health Service's Division of Nursing Special Project grants in collaboration with the American Hospital Association, the Association of Nurse Executives, and other professional organizations for the development of innovative strategies designed to increase retention of nurses in practice.

3-16 The Department of Health and Human Services should fund grants to Schools of Nursing that seek collaborative relationships with agencies to demonstrate the cost-effectiveness and quality of utilizing the nurse as a case manager who:

- assesses the patient and family needs for short-term and long-term care;
- mitigates medical costs by facilitating the patient's optimal level of independence through access to appropriate levels of care both in the hospital and in out-of-hospital settings;
- organizes and sequences those services and resources needed to adequately respond to patient's health care needs by: working with the attending physician to assess the patient's medical needs; and functioning as a liaison between the patient and specialized facilities and other providers.

3-17 The Department of Health and Human Services (HHS) should fund tuition and stipend grants for students in innovative nursing education programs, which offer advanced degrees in nursing as a first professional degree in nursing in order to:

- meet future health care provider needs as defined by HHS.
- address the shortage issue by stimulating interest in nursing careers among those in a non-traditional, older population, who may seek professional nursing as a second career.

3-18 The Health Care Financing Administration should restructure the Medicare and Medicaid reimbursement systems to allow for direct reimbursement to professional nurses caring for persons with HIV-related illnesses and other chronically ill patients in acute and community care settings.

3-19 The Public Health Service's Office of Minority Health should identify funding for recruitment of minorities into advanced levels of nursing education programs.

3-20 Congress should amend the Nurse Training Act to include the provision: that up to 85 percent of a borrower's loan plus interest would be canceled at the rate of 15 percent for each complete year of full-time employment as a professional nurse.

National Health Service Corps

It is estimated that 34 million persons in the United States live in areas or in groups designated as health care shortage areas or groups. To meet the needs of these underserved areas, the services provided through the National Health Service Corps (NHSC) have been of extraordinary value over the last 18 years. NHSC has helped communities obtain qualified health care providers by providing scholarships (tuition abatement) in return for a commitment to work longer in a medically underserved area. This placement effort was begun to complement federal, state and private programs which were aimed at expanding student enrollment in medical schools. This expansion was an answer in part to resolving the severe national shortage of health care workers. The primary mission of NHSC since its inception in 1970 has been to provide primary care services to isolated or underserved areas and to populations which for a variety of reasons, such as economic or geographic barriers, minority status, language, cultural, or other constraints, are unable to obtain basic health care.

The majority of personnel serving in NHSC have been physicians though it also includes dentists, pharmacists and podiatrists. In 1986, the program reached its peak field strength of approximately 3,200 individuals. Its current enrollment of 2,800 is serving in federally funded Community Health Centers (CHCs) and Migrant Health Centers (MHCs) as well as facilities operated by the Indian Health Service (IHS), the Bureau of Prisons (BOP), and through private practice arrangements. As of November 30, 1987, 508 NHSC physicians and 27 NHSC dentists were serving in facilities within the 30 standard metropolitan statistical areas (SMSAs) with the highest incidence of AIDS cases. However, due to the elimination of scholarships since 1981, the number of obligated physicians will be decreasing to fewer than

100 NHSC providers available for assignments by 1994, at a point when service needs for these underserved populations will be extremely high.

Persons with HIV are now underserved in many parts of the country and the increasing caseload will create further strains in the nation's health care system. During the Commission's site visit to Belle Glade, Florida, the need for NHSC was strikingly evident. A single NHSC physician provided the main health care services available to the entire community of HIV-infected residents and their families, as well as the area's migrant population. This area and other areas like it will face a health care crisis when NHSC physicians complete their obligation and leave without being replaced.

On December 1, 1987, Public Law 100-177 was signed which provides for the establishment of a new federal loan repayment program, a state repayment loan program, and includes special repayment provisions for previous NHSC scholarship recipients who have failed to comply with their service obligations. The scholarship program provides tuition fees and stipend support to enable medical and dental students to complete their professional education. However, it is expected that these programs will make loans available to only 40 persons and return to service a limited number of earlier scholarship recipients. This is inadequate to meet projected needs.

Obstacles to Progress

- As the National Health Service Corps (NHSC) personnel currently serving populations in underserved areas are withdrawn, a severe health care shortage will occur.
- NHSC physicians and dentists are often the only source of health and dental care in the community.
- Health care availability through the Indian Health Service and the Bureau of Prisons, already limited, may worsen as the number of HIV infection cases increases.
- The decrease in available NHSC scholarships will make the number of health professionals available to underserved areas woefully inadequate.

RECOMMENDATIONS

3-21 The National Health Service Corps scholarship funds program should be reinstated to enlist an additional 400 primary care physicians in training per year, and provide loan forgiveness to 100 additional practicing primary care physicians per year to staff facilities in underserved areas, including HIV-endemic areas.

3-22 The National Health Service Corps should establish scholarships, loans, and workstudy opportunities to recruit, train, place, and retain 200 nurses per year to staff facilities in underserved areas, including HIV-endemic areas.

3-23 Individuals who received National Health Service Corps funding for all or part of their professional education and who have defaulted on their subsequent service obligations, should be offered the option of serving in HIV-endemic areas to meet their outstanding obligations.

3-24 The National Health Service Corps should establish scholarships, loans, and workstudy opportunities to recruit, train, place, and retain 100 master's degree level social workers per year to staff facilities in underserved areas, including HIV-endemic areas.

3-25 The National Health Service Corps (NHSC) should permit specialist physicians who have not as yet met their NHSC scholarship service obligations to fulfill these obligations in an underserved, HIV-endemic area. Those specialties most appropriate to HIV-related care, such as infectious disease or internal medicine, should receive priority.

3-26 The National Health Service Corps should ensure that all its professional staff are provided with education and training in the diagnosis, treatment, and prevention of HIV infection, particularly in HIV-endemic areas.

3-27 The National Health Service Corps should provide scholarship funds at the undergraduate level to minority students to allow more minorities to continue their education through the professional degree level, with repayment of these scholarships through service in underserved, HIV-endemic areas.

3-28 The Secretary of Health and Human Services should ensure that minorities are represented on federal decision-making bodies in order that cultural characteristics are recognized appropriately. All new federally funded HIV treatment service programs should include local advisory boards with appropriate minority representation.

Section II. Health Care Worker Education

Numerous privately and publicly funded organizations are developing training resources for health care providers, distributing health education pamphlets, and research monographs, and publishing books, articles, and newsletters in an attempt to share information about HIV throughout the health profession community.

Agencies and organizations which are attempting to coordinate or develop HIV information exchange include:

- The Centers for Disease Control AIDS Clearinghouse;
- The Centers for Disease Control AIDS Hotline;
- The Health Resources and Services Administration AIDS Education and Training Centers Program;
- The Health Resources and Services Administration Area Health Education Centers Program;
- The National Library of Medicine;
- Medical societies, specialty organizations and professional associations;
- HIV advocacy and support groups; and
- several commercial ventures.

Community planners and administrators who are in the position of designing treatment systems to meet significant anticipated increases in their patient populations need access to research findings which suggest the most humane and cost-effective approach to HIV-related care.

Information about the National Institutes of Health (NIH) experimental treatment protocols is currently disseminated through a private contractor. Information about experimental drug trials funded outside NIH is generally not centrally collated for retrieval by practicing providers, researchers, or the public.

Obstacles to Progress

- Many health care providers have not received adequate education about the psychosocial needs associated with death and dying, and also have not received sufficient education about the psychosocial aspects of human sexuality. As a result, some providers are limited in their ability to meet these specific needs in HIV-infected persons or their loved ones.

- In communities where the prevalence of HIV infection has been relatively low, primary care physicians who encounter HIV-infected patients in their practice may have no awareness of central sources of information about the disease. Because they do not know where to direct their questions concerning treatment modalities, evaluation and management may be suboptimal and unnecessarily expensive.

- Information about experimental HIV treatment protocols is not adequately communicated to those who need it. Information about existing treatment protocols is being compiled by a private organization, the American Foundation for AIDS Research, with support through a National Institute of Allergy and Infectious Disease subcontract. However, many practitioners and persons with HIV infection are not aware of this. Information about experimental protocols not funded by NIH is more difficult to acquire and at this point appears incomplete.

RECOMMENDATIONS

3-29 The federal government through a central database/hotline should provide:

- treatment information for those with HIV and for health care professionals.
- experimental treatment protocol information to practitioners and the public.
- linkages with international databases.
- clearinghouse for health services.

3-30 The Liaison Committee on Medical Education of the Association of American Medical Colleges and the American Medical Association, which accredits medical colleges, should immediately determine how medical colleges are modifying curricula to assure adequate education about prevention, diagnosis, and treatment of HIV infection.

3-31 The American Association of Medical Colleges should develop and circulate to member institutions a model plan for curriculum structure, which medical schools can adapt to develop individualized programs best meeting local needs and circumstances. The Health Resources and Services Administration's Multidisciplinary Curriculum Development Conference on HIV Infection, in November 1987, produced consensus recommendations which may be useful for this purpose.

3-32 The Special Initiative Funding of the Area Health Education Centers (AHEC) Program should be increased to include funds to establish communication channels and outreach programs to reach nurses and other health care providers in all settings within the region to disseminate updated information concerning the care of HIV-infected persons. AHECs should establish appropriate training strategies for care providers within their region to learn about HIV, including train the trainer and clinical hands-on experience strategies.

3-33 The state regulatory agencies that issue licenses for health care providers should strongly urge completion of comprehensive continuing education programs about HIV, with particular attention to prevention, diagnosis, treatment, and infection control. Those states that require continuing education of health care providers for licensure should include HIV infection. Professional societies should assume the responsibility for seeing that every health professional is educated concerning HIV infection.

3-34 Health professions schools should provide faculty development programs to assure that faculty are adequately prepared to educate students about aspects of HIV. Faculty development grants should be provided by the federal government, to be administered by the Health Resources and Services Administration's Bureau of Health Professions, with matching state funds.

3-35 The Department of Health and Human Services should require any HIV educational programs which receive federal funds for both professional and non-professional health care providers to include culturally relevant and sensitive curriculum and instruction.

3-36 Health professional organizations and societies should immediately develop plans for assessment of their members' HIV-related educational needs, design ongoing educational programs to overcome identified deficiencies, and periodically evaluate effectiveness of these programs. Where possible, educational offerings should be multidisciplinary and incorporate hands-on experience.

[See also (3-53), (3-54), and (3-55) in following section.]

Section III. Health Care Worker Safety

The American health care system is based on the work of the fine women and men who daily provide quality care for sick people, many times in difficult circumstances. The Commission appreciates that their dedication and sacrifice contributes greatly to the health of all our people.

The nature of health care providers' work puts them at risk of exposure to a number of infectious diseases, therefore efforts to minimize that risk should be a high priority on this nation's health care agenda. According to the Centers for Disease Control (CDC), there are several routes through which a health care worker is considered to have an "exposure" to blood or blood-contaminated body fluids, and possibly to HIV infection. They include:

- parenteral (e.g. needlestick, cuts);
- mucous membrane (e.g. splash to the eye or mouth);
- cutaneous, involving large amounts of blood or prolonged contact with blood, especially if the exposed skin is chapped, abraded, or afflicted with dermatitis.

Health care workers have responded to the HIV epidemic in a responsible and compassionate manner even in the absence of comprehensive research and established guidelines and procedures for HIV infection control. Many of their concerns have been treated casually by those responsible for providing for their general safety and health in the workplace setting, including administrators, regulators and government officials at the federal, state and local level.

The health care professional is often thought of as being confined to the physician, the nurse, and perhaps the laboratory personnel. CDC considers a health care worker as any person, including students and trainees, whose activities involve contact with patients or with blood or other body fluids from patients in a health care setting. The full range of health care workers -- including nurses' aides, home care workers, the chaplain, volunteers, laundry workers and other hospital housekeeping personnel -- needs to be considered when developing infectious disease control procedures and training programs.

In particular, those who provide pre-hospital emergency care -- police, fire fighters, emergency medical technicians, paramedics -- should be considered as health care workers who may require particular methods of precaution that reflect their relative risk when delivering emergency health care.

The Commission heard considerable testimony regarding the quality and availability of the equipment used and the garments worn by health care providers. We heard that in some facilities gowns, goggles and shoe covers often are not inspected and that procurement procedures are often designed to purchase the least expensive equipment without consideration for effectiveness. In other facilities, equipment and required supplies are not available in the quantities needed. Virtually nothing has been done to address the concerns of emergency response workers who must perform life-saving functions in the most unaccommodating environments.

Health care workers expressed considerable concern that infectious disease control efforts in general have not been very effective in this country. This is evidenced by CDC data which reveal that between 12,000 and 15,000 health care workers a year become infected with hepatitis B, leading to over 200 deaths a year.

Because HIV is in some ways similar to hepatitis B, a number of studies were undertaken to assess the risk of HIV infection to health care workers. Additional information regarding the extent of actual occupational exposure has been gathered by other sources such as the CDC AIDS surveillance system and case reports published in medical literature.

Most hospitals are not funded to do the necessary research on the full extent of risk to health care workers. Therefore, the studies that are being reported are limited in scope, leading sometimes to contradictory information about the extent of risk and the safeguards that need to be implemented.

Among health care workers, however, there is a general consensus that more, and larger, studies of the extent of risk of HIV infection need to be undertaken in order to resolve the persistent questions and build a level of confidence in those on the front line of providing health care to the nation's sick, especially those with infectious diseases.

Early studies and reports have indicated that the risk for occupational transmission of HIV in the health care setting is less than one percent; that is, of all possible exposures, fewer than one percent actually lead to seroconversion. If this pattern continues, the level of risk for occupational exposure to HIV infection is comparable to or lower than other workplace risks that health care workers have been taking for years.

For over 18 years various governmental agencies, particularly CDC, have been active in developing guidelines and recommendations to prevent patient-to-patient, health care worker-to-patient and patient-to-health care worker transmission of infections. A variety of health professional organizations have also been involved in health education and promotion, as well as infection control and prevention for their members.

There is a great need for administrative and employment policies instituted by health care employers and administrators that provide effective approaches to the complex problem of exposure to blood-borne infectious diseases among health care and support workers. Structured infection control training, and strict requirements for compliance in the health care setting cannot be overemphasized.

A multifaceted program that includes ongoing research and innovative educational and training techniques could provide valuable information on how best to accomplish the goals of ensuring that workers at significant risk are provided with appropriate protection and are trained in the need for safe work practices.

Public Health and Safety Workers

There is great concern about possible on-the-job exposure to HIV among certain public health and safety workers, particularly ambulance personnel, police, fire fighters, correctional officers, sanitation workers, and custodians.

Many of these workers come in direct contact with the blood of individuals on a regular basis, either when providing emergency medical care or in confrontational or violent situations. Others deal regularly with waste products, blood contaminated body fluids and used hypodermic needles.

Development of precautions against HIV for these workers has been less than adequate. Precautionary measures issued by various governmental agencies for all workers who may come in contact with HIV and other blood-borne diseases are generally considered to apply to emergency response workers as well, but have not been presented to those workers in a systematic fashion.

Emergency response personnel are particularly concerned about their inability to determine whether they have been exposed to HIV through contact with asymptomatic infected individuals. In some states, confidentiality laws prohibit hospitals from releasing information about a patient's HIV status, leaving these workers to wait several months until their own blood tests confirm whether or not they have contracted the virus. This long delay in notification causes great anxiety and has a devastating effect on personal relationships with family members.

Extent of Risk

CDC and other experts have determined that the primary risk of HIV transmission to health care workers in the health care setting is by blood and blood-contaminated body fluids, and the major mode of transmission is percutaneous needlestick exposure. Other studies confirmed that needlestick exposure is the main route of HIV transmission to health care workers.

Some current studies conclude the risk of infection from a single needlestick exposure to HIV infected blood is 0.5 percent (one in 200). The risk of HIV infection over a lifetime of needlesticks could be substantial. However, to put this level of risk in perspective, the rate of infection following a single needlestick exposure to blood infected with hepatitis B virus is 10 to 15 percent, approximately 10 to 30 times greater than the risk of HIV. Further studies to reassess HIV risk to health care workers are urgently needed in light of recently released research. Fortunately, most needlestick injuries are preventable in the opinion of most practitioners.

Health care workers, themselves, admit that all too often the risk of exposure to HIV or other infectious diseases is caused by the cavalier approach taken by some workers as they perform their duties, particularly when they are not properly using infection control procedures.

Risk of other HIV-related infections is also of significant concern to health care workers. Patients whose immune systems are compromised by HIV excrete in relatively high concentrations many other agents, including cytomegalovirus (CMV), hepatitis B virus (HBV), herpes simplex virus type 2 (HSV-2), and Epstein-Barr virus (EBV). Tuberculosis is also a frequent infection in HIV-infected individuals. Even though current studies indicate that there is no difference in the prevalence of these secondary infections in health care workers with high exposure to AIDS patients and those with low or no exposure, the Commission continues to be concerned about the effect of such exposure on health care workers, particularly those who are pregnant.

Policies for Prevention of Transmission of HIV

CDC has developed basic policy recommendations for prevention of HIV transmission in the health care setting. These recommendations, which call for the use of Universal Precautions, are designed to emphasize the need for all health care workers to consider the blood and blood-contaminated body fluids of *all* patients as potentially infected with HIV and/or other blood-borne pathogens and to adhere rigorously to infection control precautions for minimizing the risk of exposure to blood and body fluids of all patients.

This represents a major difference in the way body substance precautions were taken in the past. Under the old system the health care worker was required to identify the patient and the specific infection in order to implement appropriate infection control procedures.

It is generally felt at this time that dependence on HIV blood testing as an infection control procedure or to screen all patients for the purpose of preventing occupational transmission of HIV is not effective and in fact may interfere with other means of preventing occupational transmission. However, the use of testing for the early diagnosis, medical management, care, and understanding of the patient is appropriate.

There continue to be certain physical barriers, engineering barriers, financial and behavioral barriers to compliance with Universal Precautions and other infection control procedures. Development of an enforceable infection control standard to protect health care workers from all blood-borne diseases is greatly needed. CDC does not have the authority to enforce hospital compliance with its recommendations.

The Occupational Safety and Health Administration (OSHA) in the Department of Labor (DOL) is generally responsible for the development and promulgation of occupational safety and health standards and for the effective enforcement of such standards. In conjunction with the Department of Health and Human

Services, DOL issued a Joint Advisory Notice to over 600,000 employers designed to provide some basic recommendations for protection against occupational exposure to HIV and HBV. OSHA has also begun inspections in response to formal worker complaints and general schedule inspections to examine actual work practices in health care settings, especially the extent of compliance with existing protective guidelines. Enforcement is also within the authority of the Health Care Financing Administration through its certification standards for federal reimbursement and through the accreditation process of the Joint Commission on Accreditation of Hospitals.

In addition, DOL is completing the rulemaking process on the development of an enforceable standard to protect health care workers from the threat of infectious blood-borne diseases.

The National Institute for Occupational Safety and Health, a division of CDC, is responsible for conducting research, experiments, and demonstrations relating to occupational safety and health and for making recommendations concerning new or improved occupational safety and health standards. This agency would be responsible for doing research on the efficacy and adequacy of personal protective equipment, yet very little progress has been achieved to date.

Expeditious and coordinated consideration of these efforts at the federal level should set the tone for state, local, and personal responsiveness.

Policies for Infected Health Care Workers

Health care facilities should have policies for their HIV-infected employees. It is important that institutional policies protect the employment status of the worker, while balancing the responsibility to provide safe care to patients. Without such protections, infected workers will be reluctant to identify themselves.

In general, policies that govern any other HIV-infected worker could apply to the health care worker. The clear exception is when the health care worker poses the risk of transmission to a patient during the performance of an invasive procedure. Also of concern is the time period when the risk of transmitting a secondary infection exists. Some health care institutions prohibit HIV-infected health care workers from participating in direct patient care, and assign them to other duties instead.

The consensus of witnesses is that infected health care workers should be evaluated in conjunction with their family health care providers, and any changes in work assignment or responsibilities should be done in a manner appropriate to each one's medical condition. In considering any job reassignment, an infected worker's health should be protected against exposure to secondary infections wherever possible.

Obstacles to Progress

Some obstacles to progress are:

- Data are lacking which could be obtained from large-scale studies to determine the risk of transmitting HIV and other infectious diseases in the health care setting.
- Training and tradition, tend to stand in the way of health care workers assimilation of and compliance with infection control procedures.
- Pre-hospital emergency care providers (paramedics, fire fighters, and police) have an immediate and continuing need for more education about infection control because their frequent exposure to blood and body fluids in their handling of all types of patients in uncontrolled settings places them at elevated risk of exposure to the virus.
- There is a lack of current, high-quality education and training materials.
- Health care workers who have not had recent formal educational training about AIDS/HIV have gaps in their clinical knowledge.
- Health care professionals who have significant fears, phobias and other psychological blocks are inhibited in their care of HIV-infected patients, and tend not to use appropriate infection control practices.
- Certain state laws prohibit hospitals from divulging information about a patient's HIV status, even to emergency response personnel who have had an exposure to the blood or blood-contaminated body fluid of the patient.
- Costs of implementing precautions can be significant, such as training costs, costs of better quality supplies, engineering modifications, and updated and current educational materials.
- Current technology for equipment design is deficient. Some equipment may increase the risks of occupational exposure.

RECOMMENDATIONS

3-37 The federal government should provide incentives and funding for the development of systematic, large scale studies of the occupational risk of HIV and other blood-borne agents in the health care setting and the efficacy of Universal Precautions.

3-38 The National Institute for Occupational Safety and Health should facilitate cooperative arrangements among health care employers and federal and state agencies to standardize requirements for research efforts in order to maximize the usefulness of the results. Flexibility should be maintained wherever possible.

3-39 The National Institute for Occupational Safety and Health, in cooperation with other concerned bodies, should support and conduct studies that document the level and particular types of exposure risks that are taken by emergency and other non-institutional personnel and how they can be prevented.

3-40 The Department of Labor should move expeditiously to develop a permanent and enforceable standard covering blood-borne diseases, with penalties for noncompliance, to protect health care and other workers whose jobs involve exposure to blood and blood-contaminated body fluids.

3-41 All health care professionals should be required to be certified in infection control knowledge and to participate in an appropriate education program.

3-42 All institutions and agencies employing health care workers should require adherence to Universal Precautions or other infection control procedures in performance standards and in workers' evaluations.

3-43 The Department of Labor, through the Occupational Safety and Health Administration, or the Joint Commission on Accreditation of Hospitals should require that all health care facilities make infection control devices and supplies available in all patient care areas. Institutions should be required to document that adequate stocks and timely disposal of filled infectious waste containers are accomplished.

3-44 Legislation is needed in some states to permit hospitals to notify health care workers, who in the process of providing health care have had an exposure, as defined by the Centers for Disease Control, to the blood or blood-contaminated body fluids of any patient, of that patient's infection status. Notification should be made in such a way to protect the confidentiality of the patient while ensuring prompt notification to the health care worker. All future laws designed to protect confidentiality should include this exception to absolute confidentiality.

3-45
9-102 If, in the process of providing health care, a health care worker is exposed to the blood or body fluids of any patient, the health care worker has the right to know the infection status of that individual. Consent agreements obtained in the traditional health care provider/patient context will normally provide for this. In the unusual case of denial of consent, competent medical authorities should make the determination whether testing should be done and, if done, should note the rationale in the medical record.

3-46 The Department of Health and Human Services should provide increased funding for the timely development of curriculum changes and new training materials tailored to address the needs of management, health care personnel, and others who are involved in providing care to HIV-infected and AIDS patients.

3-47 The National Institute for Occupational Safety and Health should provide research funds for developing new techniques to decrease risk to health care workers, particularly through equipment design modification. This research should be integrated and should emphasize utilization with Universal Precautions. It should be coordinated in a way to help the entire range of health care providers, including volunteers. The results of such research should be communicated to practitioners in a coherent and timely fashion.

3-48 All employers of health care workers should have prospective personnel policies for employees who may have occupational exposure to blood and bodily fluids in order to ensure equitable treatment, appropriate medical surveillance, care and monitoring should the employee become infected.

3-49 All employers should ensure that employees infected with HIV have access to the same sick, disability, and vacation leave as employees with other medical conditions.

3-50 Research institutions should give health care workers who become infected on the job priority in treatment programs as new drugs become available and other medical interventions are developed.

3-51 The Centers for Disease Control should encourage voluntary HIV screening programs to monitor and better understand events that cause infection and to provide maximum support and assistance to workers who become infected.

3-52 The National Institute of Mental Health should offer research grants for the purpose of studying the complex psychosocial issues which preclude assimilation of, and compliance with, infection control guidelines by health care professionals.

3-53 The Department of Transportation should expand the section of the National Standard Curriculum for the First Responder Course, the Emergency Medical Technician-Ambulance Course, and the Paramedic Course that pertains to communicable diseases so that appropriate infection control techniques, including those that protect against HIV infection are included. States should adopt at least that portion of the National Standard Curriculum which pertains to communicable diseases.

3-54 The certification process of pre-hospital care providers should confirm a sufficient knowledge base about infection control and HIV. In addition, states should incorporate a section on communicable diseases and infection control into their continuing education requirements for emergency care providers, (i.e., first responders, emergency medical technicians, paramedics, police, and firefighters).

3-55 Institutions which benefit from the services of health care volunteers should assume responsibility for assuring that they are educated about HIV, including epidemiology, modes of transmission, and methods of infection control.

CHAPTER FOUR: BASIC RESEARCH, VACCINE, AND DRUG DEVELOPMENT

Basic biomedical research continues to make vast and unprecedented advances in key scientific areas directly applicable to the HIV epidemic. However, significant obstacles confront both the scientist seeking a cure, and the individual with HIV infection seeking treatment. Our national system of research programming and funding is not equipped to reorganize rapidly in response to an emergency. The process of individual initiatives by scientists, followed by peer review, while essential, produces results at a rate too slow to be understood or accepted by a country at risk. Innovative initiatives are urgently needed that will both maintain scientific integrity and shorten the time from discovery to trial, and from trial to safe and effective treatment use.

In its hearings on research issues, the Commission identified several areas of serious concern. Foremost among these is the need for broader basic research activity to more rapidly model and develop a broad range of anti-viral and immune modulating drugs and the need for immediate implementation of broadly accessible clinical trials of all potentially therapeutic agents.

In the area of basic research, other problems identified were:

- the need to free federally sponsored research from many of the bureaucratic restrictions that delay progress and constrain exploration.
- the need to create new ways of thinking about basic biomedical research and science education and to establish them as much higher funding priorities.
- the need for greater collaborative research, both nationally and internationally.
- the need to upgrade many of America's aging research facilities and properly equip them for HIV research.
- the need for an even greater emphasis on basic biology, virology, and immunology.
- the urgent need for the establishment of a data base that would provide a description of the natural course of the disease from which "historic controls" might be derived for research on the full spectrum of HIV-related illness.
- the need for greater communication of research results, both within the research community and to the general public.

In the areas of drug and vaccine development, problems include:

- the need for increased access by a broader spectrum of the infected population to a greater variety of experimental treatments.
- the need to eliminate whenever possible the use of placebo-controlled trials in patients whose disease is immediately life-threatening.
- the need for a public information system that would collect and make available current information on drug development and open clinical trials.
- the need for direct federal support of quality-assured community-based drug trials.
- the need to set aside counterproductive competition as much as possible in favor of greater collaboration among pharmaceutical industry members, and between industry and government, especially in times of medical emergencies.
- the need for additional Food and Drug Administration (FDA) resources to process more rapidly all HIV-related applications without compromising standards of safety or efficacy or causing delays in the review of promising drugs for other diseases.

Hearings on these and many additional research problems yielded the following information and recommendations.

Section I. Basic Research—The National Institutes of Health

AIDS is a complex and aggressive biomedical syndrome which was initially recognized in this country at a time when there was no knowledge of what caused the disease, how it was transmitted, or how it could be stopped. There were no therapeutic drugs with known effectiveness, no vaccines, and no hope for early intervention in what seemed to be an endlessly escalating process. When an etiologic (causative) agent was identified by Dr. Robert Gallo at the National Cancer Institute (NCI) and Dr. Luc Montagnier at the Pasteur Institute in Paris, it was found to be a retrovirus, a type of virus about which comparatively little was known.

Within a short time, however, the research community responded to the challenge posed by the new disease by attacking it on many fronts. Even before the virus was isolated and the etiology of the disease established, many of the complexities of the syndrome had been delineated, and information had been gathered on transmission and possible co-factors. As soon as HIV was identified, intensive laboratory work began with "off the shelf" drugs to find agents that might be viricidal or interfere with viral replication. Trials of promising drugs and vaccines are underway. That these successes were achieved relatively rapidly was due to the presence of a major research infrastructure that worked -- one that was built upon several decades of serious research commitment at the National Institutes of Health (NIH).

America's investment in basic research can be broadly categorized as an investment in research and an investment in researchers. The former includes direct federal, state, and local funding for materials, facilities, and programs. The latter includes investment in training and support mechanisms which enable investigators to pursue innovative ideas. This research takes place on university campuses, in medical institutions, and in independently sponsored research centers. Although other federal sources exist, the distribution of federal funding for research programs in these varied sites is centralized in NIH. The largest proportion (87 percent) of HIV research funding provided by NIH is given to institutions and individuals by means of direct grants or contracts.

The advances made to date in research rest on a foundation of research excellence established many years ago at NIH and accelerated in the 1970's by the "War on Cancer," primarily within NCI. During this period, funding was increased in the areas of epidemiology, molecular biology, microbiology, virology, immunology, genetics, and pharmacology, in an effort to find a "magic bullet" that would cure malignancies.

In the early years of the HIV epidemic, NIH scientists answered the challenge by turning their research efforts to the new disease even though technically they were funded to do other work. As knowledge of the severity of the problem increased, funding followed so that research at NIH, the universities, and medical centers could continue and broaden in order to explore the disease more aggressively.

Initial NIH funding for AIDS research was authorized by Congress in 1982 at $3.5 million. During FY 1988, NIH funding for HIV-related research is expected to reach almost $468 million, an 80 percent increase over the previous year, over 13,000 percent higher than in 1982. Of these funds, $407 million will be given in grants to support programs in universities, medical centers, and other extramural institutions, as well as to individuals. The remaining $61 million (13 percent of the total) will support intramural research at the National Institute of Allergy and Infectious Diseases (NIAID).

While the federal government has allocated large sums of money to meet the research requirements of the epidemic, and while a great deal has been learned in a relatively short time, pressing research needs still exist.

HIV-related basic research is expected to have high yield benefits to Americans who suffer from cancer, viral diseases, and immune diseases, which collectively kill an estimated 650,000 individuals each year. Research areas that require additional long-range funding include:

Virology and molecular biology: What more can we learn about viral activity and structure so that vaccines and anti-viral drugs can be rapidly and efficiently modeled and developed? Until recently, very little was known about retroviruses and lentiviruses, and though we are still only on the threshold, our knowledge is increasing rapidly.

Immunology: How does HIV damage the immune system? Why do some individuals remain healthy for so long after acquiring the virus, while others rapidly decline? What can be done to stimulate or support the immune system of the infected individual so that he or she will remain healthy?

Cell biology and host genetics: What viral mechanisms function in infected cells during the viral replication cycle, and how can we interfere with these mechanisms? What genetic co-factors, present in some individuals and not others, influence susceptibility and resistance to infection with HIV and the occurrence and rapidity of progression from a symptom-free state to overt disease?

Pathogenesis: What are the mechanisms by which HIV spreads from cell to cell within the body, kills certain cells and interferes with the normal function of others, and undermines the host immune response to many serious opportunistic infections?

Reagents, Animal Models, and Research Information Exchange

For information obtained in different research laboratories to be comparable, certain common resources must exist. Biologic materials such as viral strains, genetic probes, polyclonal and monoclonal antibodies must be standardized and made widely available.

To date, adequate animal models have not been developed for human HIV-related research. An appropriate model is one in which the animal can be infected with HIV and can develop disease similar to that produced by HIV infection in humans. In this way, experiments critical to our understanding of the virus, and of disease progression can be conducted without the use of human subjects. Difficulties with animal models for HIV research persist. Chimpanzees, for example, can be infected with HIV, but, to date, have not developed AIDS. In addition, chimpanzees, the only primates that can be infected with HIV, are an endangered species. Their breeding, care, and use in experiments must be carefully monitored by strict application of ethics and peer review, and they should be used only when there is no other alternative. It is important to ensure that experimental animals are treated humanely and used as sparingly as possible. Progress against HIV would be achieved much more slowly, at best, if animal studies were not permitted.

Simian Immunodeficiency Viruses (SIV) are a group of viruses very similar to HIV-2 which infect rhesus macaques, a possible animal model candidate. In addition, SIV and HIV are lentiviruses, a virus characterized by a long latency period and slow progression of disease. Animal studies in lentiviruses are well documented, and use of these models may prove valuable correlates to HIV. In addition to SIV, candidate viruses include visna-maedi (sheep), caprine arthritis encephalitis virus (goats), and equine infectious anemia (horses). Ideal animal model HIV research would use small animals that can be relatively easily and inexpensively maintained (e.g., mice). As these animals may be infected using genetically altered materials, issues such as biocontainment and liability would require serious attention.

Work with virus-infected animals requires the strictest application of proper biocontainment procedures to protect research workers. Additional obstacles to developing an appropriate animal model for HIV infection and AIDS include criticism from organizations concerned with animal rights, and a decrease in the animal population overseas, resulting in ethical and legal restrictions against both animal importation and conducting research in the animals' native setting. Researchers foresee long delays in the development of HIV drugs and vaccines, especially for use by pregnant women, if animal research is precluded.

Witnesses before the Commission indicated a need for better mechanisms of information exchange and communication about work in progress, especially in basic research, but noted that competition often precludes such exchange. Within the federal government, the importance of interdepartmental communication on research programs is underlined by the HIV-related research being conducted at the Department of Defense. Research from the Strategic Defense Initiative (SDI) has, as a side benefit, produced valuable medical advances that may be useful in the fight against the HIV epidemic. One project under study is a dye laser system, which has been found capable of destroying certain viruses within the blood. Another spinoff of the SDI applied technology program is the development of a virtually impenetrable yet pliable material which will be used to make protective gloves that could be worn when conducting surgery or other medical procedures.

Several research witnesses testified that research liability problems should be addressed by the Commission because they create serious obstacles to research. Witnesses indicated that some institutions have been reluctant to undertake HIV research until such liability problems have been resolved, fearing the cost of liability protection or liability actions would be unaffordable. Basic research liability issues relate primarily to worker safety, and are of special concern to those individuals working with live virus or virus-infected animals.

Facilities

HIV has added an increased burden to our already overstrained research facilities. Many scientists believe that our research efforts have been slowed because of outdated and antiquated facilities. Work with viruses, viral concentrations, genetically altered and virus-infected animals must be done in highly controlled settings. The model developed for expanding such research includes construction of containment laboratories with a P-3 level of biosafety or modification of existing labs. At the beginning of the epidemic, very few of these facilities were in existence.

In the research community outside NIH, few universities and research institutions have funds immediately available to create or convert facilities for HIV-related work. The cost of upgrading existing laboratories to P-3 level is approximately $250,000 per laboratory. Many laboratories now exist around the country that could be upgraded in this manner, providing space for additional HIV-related research. This diverse pluralistic distribution of research space was highly recommended by several witnesses as offering the greatest potential for discovery.

Testimony suggested to the Commission that federal funding be supplied to establish regional centers for basic and applied research in retroviral diseases. These centers would be located in a university or a research institute where a critical mass of expertise already exists, and the existing research team would be organized and expanded for maximum interaction under the leadership of an appropriate investigator. The enlarged facility would be optimally equipped for this work. It would provide an appropriate environment for training of graduate students and postdoctoral fellows, and would ideally be able to share a portion of its facilities with qualified visiting researchers from outside the parent institution who lacked facilities to advance their own research. Such centers would have a great impact by providing opportunity to young researchers.

A highly specialized type of facility that is in very short supply is a laboratory equipped for advanced research on the structure of protein constituents of viruses such as HIV. These studies involve the art of making crystals of these proteins and mapping the internal structure of the protein molecule by the study of their X-ray diffraction patterns. Knowing these structures will greatly facilitate the development of antagonists to the functioning of these molecules in the course of disease development.

In order to conduct rapidly expanded research on HIV that is safe and scientifically expedient, facilities and instrumentation must be brought up to date. Funds for this type of upgrading come primarily from the federal government.

NIH last received major construction appropriations in the late 1960's. Much of the construction authorization for the research institutes has since expired. Institutes within NIH used to have independent construction authority but only three institutes are currently able to authorize and grant funds for construction. NIAID, the lead agency on HIV research, is not one of them. This has created an obstacle to NIH funding of extramural university construction and reinstrumentation, as well as prevented NIH from answering its own intramural construction needs. A new AIDS research building has been planned for the NIH campus at a cost of $30 million. After two years, this building is still in the early planning stages.

The seriousness of this obstacle is exemplified by the lack of progress on the NIAID Consolidated Office Building. Currently, NIAID personnel work in leased office spaces scattered over an area of several square miles, some distance away from the Clinical Center at NIH, where patients are seen. The proposed building would be constructed under a lease-purchase agreement and would enable all HIV-related NIAID personnel to work closely together, in close proximity to the patients.

Space on the NIH campus has been set aside for the building, architectural plans drawn, and funds approved by Congress; yet the General Services Administration (GSA) has not given final approval for construction. NIH cost estimates indicate that operating costs of current leased properties exceed those of the new building. At this point in time it would require no new dollars, and may in fact save money if construction were expedited. Documents, specially requested by the Commission and supplied by NIH, indicate that calculations of net present value have been carried out for three alternatives, with the following results:

- Continue present leases—$147.2 million
- Lease-purchase on NIH campus—$95.0 million
- Federal construction on NIH campus—$97.5 million

Delay in the construction of this building is one of the most serious research administrative obstacles the Commission has encountered.

Administrative Processes

HIV was isolated in 1983 and because the disease known as AIDS was then determined to be a virus-induced infectious disease, NIH designated NIAID as the administrator for HIV-related federal research management. Much of the pre-1983 HIV research was done at NCI, and work continues at that institute. Senior leadership within NIH, especially in NIAID and NCI, responded to the challenge of the epidemic by establishing a system for organizing and funding research priorities that required almost simultaneous development and execution. Within a brief time, a new research and clinical trial structure had been conceived and implemented at NIAID that structurally paralleled that of NCI, which had been established over a period of years. The urgency and breadth of this effort is without precedent in the history of the federal government's response to an infectious disease crisis.

Witnesses critical of the NIAID response have testified that little funding was received by outside institutions until late in 1984. They believed that this was due to the lack of a preexisting administrative structure similar to that of NCI for clinical trials, and also due to the complexity of the grant funding process.

The NIAID clinical trials program has currently enrolled nearly 4,000 patients and is expanding into additional research institutions, as well as into community- and physician-oriented programs. The funding and grant making process has recently been reviewed and the "ASAP" (Accelerated - Solicitation - to - Award Program) enacted. This should cut grant review and turnaround time to less than six months. Both the accelerated grant review and community involvement in clinical trials are significant breaks with research and funding tradition. They represent an effort on the part of NIAID to respond to the urgency of the HIV epidemic and the needs of the research and patient communities. However, as stated in the Commission's interim report, a greater sense of urgency throughout the government is needed to implement the increased funds already approved by Congress and to supplement improvements already underway by NIH.

The diversity and multiplicity of HIV research projects at NIH requires management at the level of the Office of the Director. NIH recently announced the initiation of the Office for AIDS Research, which was established in April of 1988, and will eventually have 12 to 15 full-time equivalent positions (FTEs). It is operating under a current budget of $400,000 which is expected to double in the following fiscal year. The Commission endorses the Director's establishment of this office and encourages its full staffing and support.

The Commission's examination of HIV research programs has revealed that despite NIAID's commitment to rapid response, limitations in the federal system must be addressed if this nation's goal of controlling the epidemic is to be realized. One of the greatest obstacles cited by NIH administrators is the inflexibility of Office of Management and Budget (OMB) regulation of internal resource allocation and program development. Currently, OMB acts as a surrogate Secretary of HHS, in effect, micromanaging research on the institute level within NIH. The Commission favors allocating pools of resources (funds and personnel) to NIH and allowing the Director greater discretionary powers to make subsequent personnel and funding allocations to each institute. NIH witnesses have repeatedly indicated their desire to be held accountable for results and asked for greater flexibility to employ innovative methods through which to achieve those results.

The mandate of science is exploration and discovery, and this requires flexible management to allow for the creative application of ideas. Such flexibility is often difficult to achieve in a bureaucracy as massive as that of the federal government. NIH is an organization much like the National Science Foundation (NSF) in that its mission is broad scientific exploration, often in uncharted territory. However, there is a significant difference between the two in that NSF is less encumbered by layers of bureaucracy. Therefore, to allow NIH the greatest potential for discovery in HIV research, as well as in research on cancer and other diseases, the Director should have full authority and responsibility to manage the resources appropriated by Congress as needed.

Personnel and Recruitment

From FY 1984 to FY 1988, a total of 371 new FTEs were added to NIH for HIV-related activities. Over the same period, the total number of NIH personnel positions dropped from 13,493 to 12,461. This represents an overall loss of 1,032 positions, even though HIV positions have been increased. The Commission is deeply concerned that the much needed increases in HIV research personnel are being implemented to the detriment of research on other diseases. Although research on HIV must be expanded, we cannot afford to cut back on cancer or heart disease research to achieve this goal.

One serious obstacle, discussed in the Commission's interim report, is presented by FTE ceilings imposed by OMB that prohibit the recruiting of individuals above those ceilings, even in short-term emergency conditions. This contributed to both NIAID's inability to put its own programs into motion, and to the public's perception that NIAID was slow to respond. FTE ceilings are designed to limit the size of the federal government, i.e., the number of individuals working for the government who will at some point be eligible for ongoing benefits such as retirement. The approval system has entrenched inflexibilities intended to guard against such growth, but can in fact leave government agencies funded but unable to hire in response to a crisis. The National Cancer Act of 1972 created NIH short-term personnel slots that were to be filled by visiting scientists, or "cancer experts," who were not counted in FTE ceilings, as they were not likely to retire on government payroll. Four years ago, however, OMB regulations for such appointments changed, and currently these and other temporary positions count against personnel limits.

NIH administrators also indicated that, given funds and personnel positions, they are still unable to complete hiring of some individuals because of "business as usual" paperwork delays in other agencies. Although the Office of Personnel Management (OPM) has begun discussion with NIH to streamline personnel recruitment, no practical change has been noted since the Commission's interim report. The Commission favors greater flexibility on the part of OMB and OPM to allow the NIH Director the ability to more rapidly hire greater numbers of technically specialized research personnel.

Witnesses before the Commission testified that modest salaries and the lack of other incentives deter many talented individuals from working at NIH. NIH recently proposed the creation of the "Senior Biomedical Research Service," a career track similar to the federal Senior Executive Service, which would enable NIH to recruit scientists at salary levels similar to those in the private sector. The model cited for this proposal is that used by the Uniformed Services University of the Health Sciences. Legislation creating these University pay scales exempted them from standard government levels, and enabled the University to attract personnel with salaries similar to those of other medical schools. To date, the proposed Senior Biomedical Research Service has not been approved.

Additional research hiring difficulties involve a zero tolerance for poor technique, which, when working with live virus, could prove fatal. This, coupled with the long hours, close quarters, and poor salaries, also contributes to personnel hiring delays.

Grant Processing and Research Funding

Traditionally, NIH has sponsored grants for projects that were initiated by researchers and proposed by them for funding. In response to the HIV crisis, NIH took a more centralized approach, funding a large number of specific contracts and issuing specific requests for grant applications for areas of needed research in which there was a lack of scientific interest or of readily apparent benefit. This approach has been criticized by some witnesses who felt unable to receive funds for work they thought beneficial. What is seen within NIAID as a process of taking control and targeting federal resources to underexplored areas of science is seen by some on the outside as overly restrictive and limiting research options.

Two of the most significant hindrances of NIH have been restricted spending authority and the lack of significant pools of discretionary funds that can be used in medical and scientific emergencies or immediately to implement promising programs.

Administering taxpayer money for varied yet targeted exploration in a multifocal medical and scientific crisis requires great skill and balance. Given a limited amount of total funds, and if spending is so broad that all possibilities are touched, there may not be enough money in each grant to permit a thorough exploration. If funded research is too highly focused in one area, an answer lying outside that area will not be found. Advisory councils within NIAID and NCI and the NIH Director's Advisory Council offer advice on funding direction, but some witnesses cited too few grants to younger investigators and inadequate funding for new or "unpopular" ideas. In response, NIAID has created seats on its advisory councils for community representatives and younger scientists and is considering appointing a similarly qualified person with HIV infection.

Many researchers testifying before the Commission indicated a preference for investigator-initiated research, citing its ability to offer multivaried exploration of any given topic. Many also considered highly controlled directed funding to be an appropriate response by NIAID that should be reserved for short-term emergency situations. As HIV research has been stimulated, investigators have returned to NIH with new ideas and proposals in previously underexplored areas.

Primary to all recommendations for the advancement of basic biomedical research is the concept that these funds must be new monies and not subtracted from other programs.

Basic Science Education and Research Training Grants

Testimony before the Commission cited the belief that the federal government funds the best scientists, provides access to the most sophisticated technology, and regulates to the highest standard of excellence in the world. Yet concern was expressed by members of the scientific community that the next generation will not produce adequate numbers of capable scientists willing to work in federally funded laboratories.

Current NIH training grant programs include:

- university/medical center grants, given to ten research centers;
- individual research scientist grants, to support ongoing work;
- Career Development Awards ("K Awards"), to allow a specialist in one field to acquire technical knowledge in another; and
- Research Scientist Awards, for achievement in one research area.

In the categories above, there are 200 awards of approximately $50,000 each. In addition, there are program slots for 250 summer students, each with a stipend of $1,500.

The dollar amounts listed above are the yearly maximum for these programs, although in recent years they have not always been funded at this level. Some, in fact, have been eliminated. Additional appropriations for greatly increased numbers of awards as well as the authority to execute these programs are needed.

A serious obstacle exists in that summer students studying on the NIH campus for three months are counted against the NIH FTE ceiling. This means that if NIAID wants to create research opportunities for 40 summer students, it must eliminate ten full-time positions from its staff. The summer student program represents a unique opportunity for youth, especially minority youth, to participate in government research training and to work with recognized research leaders.

Many more research personnel are needed now and will be needed in the future, as technology expands research potential. A greatly upscaled investment must be made now to guarantee the availability of researchers in the year 2000.

Obstacles to Progress

Basic research

- A lack of standardized reagents makes information coming from separate experiments difficult to assess.
- The lack of appropriate animal models for HIV research makes the application of animal research results to humans uncertain.
- Information exchange between individual researchers could be improved, as could research information exchange between federal departments and agencies.

Facilities, Administration, Personnel, and Grants

- OMB micromanagement and FTE ceilings prevent the deployment of a sufficient number of researchers to deal with pressing problems.
- The current structure of NIH management oversight by OMB and HHS means external staff are allowed to set personnel allocations at the unit program level, and to block fund shifts within categories which would contribute to the achievement of its intended goal.

- There is an inadequate number of laboratories equipped to carry out HIV work -- both at NIH and at research institutions around the country.
- A more rapid response by all elements of government is needed in order to speed NIH research efforts.
- Funds for basic research are inadequate to meet the new research priorities of the HIV epidemic.
- De-emphasis of investigator-initiated grants may threaten or constrain broad exploration in HIV research.
- Grants for HIV research projects are not made quickly enough, and funds for these projects do not allow for longer-term investigation.
- Scientists and health care professionals are not attracted to work at NIH because salary and benefit levels are not comparable to private sector institutions.

Basic science education and training

- The lack of basic science education programs in elementary and secondary education could lead to a shortage of research personnel in the future.
- There are not enough training programs in existence to supply the necessary number of future researchers.

RECOMMENDATIONS

To facilitate basic biomedical HIV-related research, the Commission offers recommendations in the following categories:

Reagents, Animal Models, and Research Information Exchange

4-1 Escalate existing efforts of the National Institutes of Health to establish a repository for reagents to be used in HIV research.

4-2 Investigate a fee-for-use basis for reagent distribution that would assist in supporting this program in private sector collaboration.

4-3 Make the development of appropriate animal models for HIV-related research an immediate and high priority, and make additional funds available to enhance primate center development.

4-4 Establish a federally funded central registry of animal model resources for HIV and other diseases.

4-5 The National Institutes of Health should develop a computerized network of all HIV-related research activities to promote greater exchange of information and data between researchers.

4-6 Increase funds to the National Institutes of Health Divisions of Research Services and Research Resources for additional animal model, reagent, and database program support.

Facilities

4-7 The National Institutes of Health intramural construction and reinstrumentation needs should be assessed and the information forwarded to the Office of the Secretary for inclusion as a high priority in future budget requests.

4-8 Construction of the National Institutes of Health Consolidated Office Building should be made a high priority and General Services Administration's approval be expedited.

4-9 The National Institutes of Health (NIH) construction authority should be reinstated during the Congressional reauthorization of NIH in 1988 to provide for the expeditious granting of funds to universities or medical centers for construction or renovation of research facilities. Construction funds should be made available in FY 1989.

4-10 Funds for construction and modification of university facilities, as well as upgrading of instrumentation, should be provided through federal matching grants.

4-11 Funds should be made available to the National Institutes of Health Division of Research Resources to upgrade or renovate 20 existing laboratories to P-3 level.

4-12 Funds should be made available for the construction of four regional structural biology centers, equipped for X-ray crystallography.

4-13 The National Institutes of Health should implement a plan for the development of regional retroviral research centers and provide renovation of construction funds for two such centers.

Administration

4-14 To better meet the research mission of the National Institutes of Health (NIH) through a facilitated management process, the Secretary of Health and Human Services and appropriate authority as required by law should mandate that the Director of NIH report directly to the Secretary for a period of two years. The

Director will receive the NIH budget directly from the Secretary, and will have discretionary authority over all subsequent allocations of personnel and resources within NIH. For the two-year period, Congress, in conjunction with the Secretary, should exempt NIH from OMB regulation of personnel and resource allocations within all of NIH. During this two-year period, NIH will continue to operate within all remaining confines of law.

Following the two-year period, Congress should authorize an independent audit to measure the effectiveness of this change. The Director and the Secretary will report to Congress, and if the change in procedure has resulted in greater flexibility for NIH to achieve its scientific mandate, it shall become permanent. If it has not, Congress should consider giving NIH a more independent funding status, similar to that of the National Science Foundation.

4-15 In order to discourage a "business as usual" response to HIV-related requests from the Department of Health and Human Services, representatives of the Office of Personnel Management, General Services Administration, and Office of Management and Budget should participate as active members of the Public Health Service (PHS) Executive Task Force on AIDS in order to assist in rapid implementation of high priority requests from PHS.

4-16 The Office of Personnel Management and the General Services Administration should respond within 21 days to HIV-related priority requests from the Directors of the National Institute for Allergy and Infectious Diseases, National Cancer Institute, and the Centers for Disease Control, or any additional director designated by the Secretary of Health and Human Services. Since the Commission's interim report, no identifiable change has occurred regarding this problem.

Personnel and Recruitment

4-17 To alleviate personnel delays resulting from current procedures, the Director of the National Institutes of Health should continue to work with the Office of Personnel Management to develop an improved package of incentives to facilitate recruiting of scientific talent.

4-18 The Director of the National Institutes of Health (NIH) should be given greater flexibility in both hiring and personnel (FTE) allocation within NIH. All new HIV-related FTEs must be *new* and not diverted from other programs.

4-19 The proposed "Senior Biomedical Research Service" should be enacted, with the necessary legislation to provide for the recruitment of scientists at salary and benefit levels competitive with private sector research institutions and medical centers.

4-20 Basic research FTE needs should be given high priority review by the Secretary of Health and Human Services and a minimum of 100 new positions should be approved for HIV-related basic research.

4-21 The Secretary of Health and Human Services should evaluate the current FTE ceilings at the National Institutes of Health in terms of the Institutes' overall ability to respond to a national medical crisis and should work with the Office of Management and Budget to determine ways to add flexibility as needed.

4-22 The Director of the National Institutes of Health (NIH) should immediately assess the incremental loss of personnel from other NIH research areas, who have been reassigned to HIV research. As these individuals are not fully accounted for in personnel allocation figures, a detailed assessment must be made of the actual impact HIV research is having on other research areas. Results of this assessment should be forwarded to the Secretary of Health and Human Services for evaluation of future resource allocation.

4-23 Research initiatives at the National Center for Nursing Research (NCNR) should be expanded. Priority should be given to areas already identified by NCNR and the National Institutes of Health, and the grant funding process for HIV-related research should be expedited. Nurses should be encouraged to submit proposals for HIV-related research to the appropriate institutes at NIH.

4-24 Fast-track recruitment programs to bring more nurses and patient care support personnel into the Clinical Center should be immediately implemented. Appropriate incentive and retention packages should be designed.

4-25 The National Institutes of Health Clinical Center should assure that the salaries of registered nurses and support personnel are competitive with local standards.

4-26 The National Institutes of Health Clinical Center should assure that an adequate ratio of support personnel to each registered nurse should be maintained.

4-27 The National Institutes of Health Clinical Center should utilize innovative nursing practice strategies to make the work environment more attractive to nurses.

Research Funding and Grants

4-28 All funds appropriated for HIV-related basic research must be new "add-on" monies and should not be transferred from existing programs.

4-29 Continue and expand support for basic science research, including virology, molecular biology, genetics, immunology, pharmacology, and pathogenesis.

4-30 To encourage the greatest possible breadth of HIV-related research exploration, place greater emphasis on investigator initiated grants.

4-31 Increase funds for "Director's Awards" at the National Institutes of Health for rapid start-up of projects to pursue new basic research ideas, and increase the upper funding limit of these awards from $50,000 to $100,000.

4-32 A discretionary fund should be created to make available to the Office of AIDS Research funds for rapid implementation of HIV-related project grants.

4-33 Implement within all of NIH the Accelerated-Solicitation-to-Award Program (ASAP) for HIV-related grant proposals.

4-34 Establish longer-term funding mechanisms for grants, expanding three-year grants to five- and seven-year terms whenever appropriate.

4-35 Maintain the HIV-related research programs in existence at the National Cancer Institute in order to allow the National Institutes of Health the greatest possible variety and breadth of research efforts, and maximize the use of existing talent.

4-36 Publicize the rules and procedures for negotiation and implementation of cooperative agreements between the National Institutes of Health and private industry.

Basic Science Education and Training

4-37 Expand and fund the National Institutes of Health training programs to levels adequate to enable qualified student researchers to continue advanced study; minimum funding levels should include:

- 350 M.D. or M.D./Ph.D. postdoctoral fellowships;
- 150 special postdoctoral fellowships for M.D.s;
- 350 graduate fellowships for Ph.D. or M.D. students; and
- 400 undergraduate or graduate health science non-Ph.D. fellowships.

4-38 Eliminate the regulation that counts short-term "expert" appointments and students participating in summer training programs against the National Institutes of Health FTE ceilings.

4-39 Enlarge the scope of training grants to include interdisciplinary programs specially tailored for HIV-related research (e.g., psychobiology and immunology).

4-40 Shift priorities in elementary and secondary education to provide greater education in biology and other sciences to young people earlier.

4-41 Develop a prestigious and highly visible set of awards to recognize both outstanding young talent and excellence in teaching in areas relating to human biology. These could include:

- Junior Science Corps Awards for elementary school students that include small monetary awards, but are primarily for recognition;
- National Bioscience Awards for high school students, that include the opportunity to work with leading scientists;
- National Science Teachers Awards to recognize professional excellence and enable teachers to spend time with leading researchers; and
- Programs should also be developed that bring researchers into the classroom, so that they can personally convey the excitement of their work.

This program could be rapidly established and funded at relatively low levels, patterned after the proposed Thomas Edison Awards for student work in areas of science that may have commercial application. One feature of the program could be a national awards ceremony that would include the President. The administrative center for the proposed bioscience awards would be the National Institutes of Health, as on-campus training programs have been in place there for many years.

Section II. Vaccine Development

Obstacles to Progress

Testimony before the Commission reported results of the Institute of Medicine's (IOM) "Conference on the Development of Vaccines against HIV and AIDS" on December 14 and 15, 1987.

A great deal has already been learned about a virus only recently discovered and vaccine models have been developed that target not only surface proteins, but also core proteins, whole virus, and virus function (as in the case of reverse transcriptase).

Despite these advances, the following obstacles were cited:

- There is a lack of basic knowledge about which cells become infected by HIV, and how to stimulate the immune system to eliminate infected cells.
- There is also a lack of adequate animal models for vaccine development.
- There will be problems with testing any vaccine that is developed.
- Research ethics are complex and undefined.
- Civil liability may slow vaccine development and evaluation.

The IOM conference presented a variety of methods currently under exploration for vaccine development and gave an overall status report. The tenor of the conference indicated that it may be many years before a vaccine that is proven safe and effective is developed. Major difficulties with binding sites were noted, as was the fact that in animal vaccine trials, although antibodies were raised, they lacked protective ability when challenged. The lack of appropriate animal models for vaccine development and the length of time projected for trials present daunting obstacles to vaccine availability in the near future. The conference concluded that prevention remains the greatest single means by which to curtail extension of the epidemic.

Ethics

Vaccine trials pose exceptionally difficult ethical questions for both researchers and participants. Essential to any blinded trial is the equal exposure to risk of disease by both the vaccinated group and the placebo group, yet medical ethics mandate counseling all patient participants to avoid the very behaviors that may put them at risk. Successfully avoiding risk delays confirmatory trial results. Vaccination causes an individual to produce antibodies to the virus, and the presence of these antibodies is currently the basis for a diagnosis of active HIV infection, thus potentially subjecting the vaccinated person to discrimination or stigma. To achieve results most rapidly, trials would be done in populations in which HIV is endemic. These are often third world or minority populations, or intravenous drug users in certain cities, raising the issue of exploitation. Because of the "window" of antibody response, an individual who tests negative at the beginning of a trial may in fact be infected, and vaccination could conceivably be injurious to his health. Vaccine trials in pediatric populations are even more ethically and emotionally complicated. All of these issues present the research and patient communities with as yet unresolved obstacles.

Liability

One of the few obstacles to vaccine development which may be more easily answered is liability, which could be addressed by legislation. Testimony before the Commission indicated substantial differences of opinion on the need for liability protection. One witness stated that only 25 to 30 vaccine liability cases have actually come to court in the past 20 years, and that the manufacturers won the majority of those cases. However, it was noted by another witness that for every case that actually reaches trial stage, there may be dozens or hundreds that are resolved earlier but that require substantial litigation time and investment on the part of manufacturers. Testimony indicated that several manufacturers were currently working on HIV vaccines, and that the threat of liability did not seem to be a great deterrent. A spokesman for one manufacturer, however, stated that unless the liability problem, real or perceived, was resolved, few if any of the manufacturers now developing HIV vaccines would be eager to bring them to market.

Several examples were presented in which a small company had initially produced a vaccine, but was unable or unwilling to market it because of liability concerns. These small companies licensed their products to larger companies that possibly had hundreds of products on the market and could therefore spread the liability risk.

The question was raised as to whether, given the cost of development, production, and trial, it would be possible to produce a vaccine that was affordable in developing nations. It was suggested that if manufacturers could or would not be willing to make the long-term investment, the government should. Having the science and technology to produce a vaccine that would save lives, and declining to do so, would seem to be ethically unacceptable.

The issue of liability protection for the physicians, nurses, and public health workers who routinely administer vaccines was also discussed. Some states have enacted protections for these health care workers, not only for strict liability, but also for simple negligence because it was ruled that not to do so would endanger the public health beyond tolerable limits.

Several models have been proposed for new legislation that would offer liability protection to manufacturers, including:

- establishment of dispute resolution mechanisms that provide compensation for vaccine injuries more quickly and cheaply than litigation, but that tie the plaintiff to a schedule of limited damages. This solution was adopted by Congress for certain pediatric vaccines.
- elimination of manufacturer liability entirely, with recourse for injuries limited to claims against the government. This was the model chosen by Congress for injuries resulting from the swine flu vaccine in the early 1980's.

The National Childhood Vaccine Injury Act was cited as a possible model for legislation. Other potential models were those states that had assumed control of production of pediatric vaccines, invoking, as in Michigan, for example, the state's sovereign immunity to such liability, and yielding the public benefit of a protected population. While it was not suggested that states begin indemnifying vaccine producers, because to do so might create a patchwork protection nationwide, state programs could be looked at as models for potential federal action.

RECOMMENDATIONS

To develop most rapidly a vaccine for HIV, the Commission recommends that:

4–42 All approaches to vaccine development should continue to be explored and developed until one or more are successful.

4–43 The basic scientific information necessary for this development should continue to be a high federal priority.

4–44 The Commission believes that any obstacle to the acquisition of an effective vaccine should be addressed and, if at all possible, removed. The Commission feels that appropriate protection from excessive legal liability should be made available to vaccine manufacturers to encourage research and development.

4–45 The National Institutes of Health, in cooperation with the Institute of Medicine, the American Medical Association, the American Bar Association, the National Medical Association, and the Justice Department, should convene a conference on liability related to vaccine and drug development. The conference should determine whether there is sufficient private sector interest in continued vaccine development. If not, then recommendations should be made as to how best to implement a full-scale government effort. A similar conference should be convened with appropriate agencies and spokespersons to investigate the ethical questions surrounding vaccine development.

4–46 The federal government should fund these conferences in partnership with the private sector.

4–47 The results of the liability conference should be submitted to Congress for the drafting of liability legislation.

Section III. Drug Development

Using a process known as rational drug modeling, it is theoretically possible to design new drugs that will have HIV-specific activity, such as interfering with viral replication. In theory, it should also be possible to design a drug that is easy to take (oral) and can cross the "blood-brain" barrier and eliminate virus in the central nervous system. This process, however, can be slow.

Within NIH, NCI has a long established history of research excellence associated with drug development. Faced with this new medical emergency, NCI geared up its off-the-shelf drug screening program, and made it available to all pharmaceutical companies, biotechnology firms, and universities for products they had already produced and had in stock. Compounds that universities or corporations felt might be effective against HIV were submitted to NCI for *in vitro* (test tube) screening. This effort resulted in the demonstration of the antiviral properties of azidothymidine (AZT), a compound submitted for screening to NCI by the Burroughs Wellcome Co.

The high level of anti-HIV activity discovered in AZT indicated that a product might be quickly developed that had the potential to stop the progression of disease in people who were already infected. When it appeared that Burroughs Wellcome lacked sufficient amounts of a key ingredient to produce enough AZT for trials, NCI, in the belief that AZT represented an extraordinary opportunity in HIV treatment, provided the ingredient at no cost.

Because no product-patent application could be filed by NIH, Burroughs Wellcome retained full market control of the compound. Many witnesses have criticized Burroughs Wellcome for the high price of the drug and NIH for contributing so greatly without retaining some control over the final cost to patients. The company indicated that its development costs were substantial, but lowered the wholesale price by 20 percent. Procedures have been instituted at NIH so that patent applications are routinely filed for all new compounds that NIH originates, as well as filing use-patents when appropriate.

By understanding how the virus works, what its physical properties are, and how virus-infected cells behave, drugs can be developed that interact with the virus at various points in its life cycle. Some witnesses indicated that enough has been learned through basic research to re-emphasize drug development through rational drug modeling, the traditional approach.

Private Sector Collaborative Research and Development

The pharmaceutical industry is playing a significant role in the development of vaccines and therapeutic agents. Hundreds of millions of dollars have been committed to such research. The private sector has a long tradition of excellent drug and vaccine development.

In times of serious medical emergency, the competition that normally fuels progress in the private sector can actually slow down the production and marketing of potentially beneficial substances. If several companies are working separately on a potential therapy that is costly and difficult to develop, they may all relinquish their efforts if the ultimate return on investment will be too low. In theory, had private companies been able and willing to pool resources and collaborate on the project, they would have eliminated the duplicated efforts, reduced cost and development time, and been able to share profits. In reality, a complex set of antitrust laws prohibit this type of collaboration.

RECOMMENDATIONS

NIH Drug Research and Development

Successful rational drug development requires additional basic research funding, and the Commission therefore recommends that:

4-48 As a near-term drug discovery measure, the National Institutes of Health should continue screening off-the-shelf compounds for antiviral and immunomodulating activity.

4-49 Research funding should be increased for the development of rational drug models for both immunomodulators and antivirals, at both the National Institute of Allergy and Infectious Diseases and the National Cancer Institute, and through their grants to universities and medical centers.

Collaborative Research and Development

4-50 The Food and Drug Administration, in partnership with the private sector, and appropriate federal agencies, should hold a conference on the subject of collaborative Research and Development in drug and vaccine development, outlining the potential benefits, risks, and legal obstacles. Participation in this conference should be sought throughout the pharmaceutical and biotechnology industries, as well as the university research community, community-based clinical trial organizations, and the National Institutes of Health.

4-51 Fund new multi-center studies where possible, to encourage collaborative research.

4-52 To encourage and reward cooperative investigation, a Nobel prize for collaborative research, both national and international, should be established.

The Food and Drug Administration

The Food and Drug Administration (FDA) is the principal consumer protection agency of the federal government. Its primary responsibility with respect to HIV is to ensure that drugs, biological products (such as vaccines and blood components), and medical devices are safe and effective.

FDA's role in the new drug approval process is to review data from the drug's sponsor and then based on information from animal and laboratory studies, FDA will grant or reject an Investigational New Drug (IND) application which allows human studies to begin; and FDA will review data from these clinical studies in order to grant or reject a New Drug Application (NDA) which permits marketing of the drug. On the date FDA receives an NDA, a "review clock" is started. By law, FDA has 180 days to approve or reject the application. During the approval process, all data from two to ten years of clinical trials are reviewed by an interdisciplinary team of scientists, as in the IND application. Some applications must be returned to the sponsors to correct errors or to provide additional data; the applications are then resubmitted to the FDA. The average approval time for an NDA is 24 months.

The order in which applications are looked at is determined with the aid of a classification system based on therapeutic importance and availability of alternative therapies. Currently, all HIV-related therapies are rated 1-AA, FDA's highest priority.

NDA Review

Witness criticism of the drug approval process dealt mainly with the length of time involved from start to finish. The problem is compounded by the fact that, currently, almost all aspects of all NDA reviews are submitted on paper. Interaction between FDA and drug sponsors during NDA review is rarely facilitated by using electronic transfer of information prepared and formatted for computer analysis.

Another obstacle cited was that a new drug approval is not always "tracked" through the FDA system by the same group of reviewers, causing delays as sponsors sought information on the status of their applications.

Treatment INDs

In spite of the best efforts of the Commissioner of FDA, with respect to newly developed anti-viral drugs or immunomodulators, the treatment IND program is not meeting the needs of persons with AIDS or advanced HIV-related illness. Treatment INDs were designed to offer some hope of access to experimental drugs to those with life-threatening disease. They allow the release of the drug on a non-clinical-trial use basis even before the end of Phase II efficacy testing, based on the FDA Commissioner's recommendation, and after safety and some degree of efficacy have been demonstrated. Although the program is well-intentioned, and does work for antibiotics and other types of drugs for HIV-infected persons, and for persons needing drugs for other diseases, the fact remains that for anti-virals and immunomodulators for HIV, the system is not working. Reasons for its failure to date include the following:

- some pharmaceutical companies are unwilling to allow their drugs to be used in this program, even when they are sought after by physicians and desperately ill patients;
- there is no information system that allows the patient or physician population to know what is available;
- methods of obtaining drugs that *are* available through this program are poorly understood and seem unnecessarily complicated; and
- some physicians are reluctant to prescribe treatment IND drugs because liability limits are not clearly defined.

Since the adoption of the new rules last year, only one sponsor has applied and been approved for a treatment IND for an HIV-related product. The status of this program has not changed since the Commission's interim report in March.

At present, while some pharmaceuticals participate in the treatment IND program with experimental antibiotics, the program is not well used for other drug types. Some representatives expressed concern that if they did apply for a treatment IND, their subsequent NDA would not be favorably reviewed. Others indicated that some form of liability protection would be necessary. Proposed solutions to the problem of liability in drug trials are similar to those discussed in connection with vaccine development. Still others indicated that wide use of treatment INDs would limit the number of individuals willing to enroll in controlled trials and thereby further delay drug approval.

Physicians indicated an unwillingness to order the drugs even if they were available because they feared that their patients would be receiving inadequately tested therapies and because of potential malpractice litigation.

The underutilization of this program is of concern to the Commission. We have received many calls and letters from concerned patients, their friends, and families seeking help. They were unable to find answers to the simplest questions about the availability of drugs. There was no centralized information network, and no one to help them through the FDA maze. If and when they did reach the right individual at FDA, they were referred to the drug companies, who, in some cases, just said no. Individuals who qualify for this program are by definition desperately or terminally ill, and it is unacceptable that this situation has languished this long without resolution.

Orphan Products

Recognition of the lack of incentives for industry to develop some products with limited commercial appeal led to the development of the Orphan Drug Act in 1983. Qualifying products must be used by fewer than 200,000 persons per year or be products for which there is no reasonable prospect of recovering R&D costs by United States sales. The central features of the Act include seven years of exclusive use, tax credits for up to 63 percent of the clinical studies, and the ability of FDA to grant special review status and development grants to these drugs.

Deterrents cited by industry in utilizing orphan drug status for HIV-related drugs include the perceived lack of adequate incentives. If the product is not expected to ever be profitable, the tax incentives in the law may not be great enough to stimulate larger numbers of companies to invest. If the sponsor seeks a patent, the market exclusivity offered to orphan drugs is not considered significant enough to be attractive. In addition, since orphan drugs are those limited to a population of 200,000 or less, immunomodulators and other drugs that can be used by a broad spectrum of HIV-infected individuals would not qualify, as there are currently projected to be 1.5 million such individuals who would be potential recipients.

Orphan drugs have traditionally been developed by pharmaceutical companies as a public service. Although industry representatives indicated a willingness to pursue areas of research for which there is limited market application, they also indicated the need to meet the concerns of stockholders, who require a reasonable return on their investment.

The Commission recognizes the need for the development of drugs for rare diseases and the assistance that has been provided by the Orphan Drug Act. Perhaps new legislation is necessary to address the question of developing drugs which can delay progression of disease or reduce infectivity but will be usable in populations over 200,000.

FDA Personnel

Current advances in basic research, both within NIH and in the private sector, have resulted in a greatly increased number of new applications for drug approvals. The number of new IND applications for HIV-related products has doubled every two years for the past four years. In addition, there are currently a large number of drugs undergoing clinical trials that will be presented for NDA review within the next two to three years.

Each of these applications requires intensive effort on the part of a consulting and review team. HIV-related drugs and products should retain their fast-track approval status without compromising the approval process of other products. Current personnel levels are inadequate to handle this load. An estimated additional 50 FTEs are required.

Training time for a medical reviewer is approximately 10 to 12 months. Currently, there is no program in place by which FDA can bring in younger personnel and train them for such work.

Medical Devices and Diagnostics

Reliability of HIV screening tests for both patient diagnosis and protection of the blood supply is essential. The approval process is slowed by the limited review staff of FDA. The staff size is constrained by both budget and a lack of a pool of qualified individuals from which to recruit.

An accurate, effective HIV antigen test, which tests for the presence of the virus itself rather than antibodies, will help eliminate false negative results of blood tests taken during the "window" period following infection, when antibodies have not yet developed. Antigen tests for HIV have been developed and await FDA approval, as do tests for HTLV-1, another sexually transmitted, blood-borne lentivirus, which can cause leukemia or lymphoma decades after infection. Blood bankers have almost unanimously indicated they should be doing this screening test on all blood donated for transfusions, to eliminate the possibility of infected blood entering the blood supply. Excellent technology is available to eliminate inaccurate test results, both at blood banks and testing sites.

Condoms and surgical gloves must be efficacious if they are to be of any practical value in prevention programs. At present, several manufacturers make these products with varying levels of quality control. FDA regulates condom and surgical glove safety, and samples batches of these products under a variety of stress tests in order to determine their integrity. The current standards of acceptability for condoms is a failure rate of 4/1,000 or less. The Commission believes that standards should be increased, and additional studies performed to determine effectiveness under a variety of conditions.

FDA Facilities

FDA facilities are currently scattered among several locations. Although the FY 1989 budget for FDA included $25 million for a new building, current projections are that at least one more building will be required to house the needed number of new full-time employees. Suggested sites include the NIH campus and the Naval Hospital Campus in Bethesda.

Working conditions at FDA are below acceptable standards. Inadequate space and underdeveloped information processing resources are two areas of serious concern, as they impact negatively on FDA's ability to respond to the epidemic. They also present a recruiting problem for FDA, as qualified individuals could work elsewhere under much better conditions. This has had a negative effect of both morale and working relations with the private sector.

FDA Image

FDA needs to educate the public about its role in setting high standards for seeking to ensure public safety and requiring efficacy of all licensed medical products. Misperceptions about FDA's work have contributed to the distrust and lack of coordination which have hindered efforts to respond to the HIV epidemic.

Obstacles to Progress

- Insufficient funding is slowing the important work of rational drug development.
- Laws that prohibit collaborative research and development among private companies may be slowing the speed of drug development.
- FDA needs to speed up its NDA process. Currently, the process is slowed by the submission of a large amount of material on paper, which means all information must be manipulated by hand. The process is also slowed by having different groups working on the IND and NDA applications for the same drug.
- FDA does not have enough reviewers to expedite the processing of HIV-related drug applications without slowing the processing of drugs for other diseases.
- Currently, the disincentives for using the treatment IND program are greater than the incentives, for both the prescriber and the manufacturer.
- Adequate information is lacking about what drugs are available under treatment IND rules.
- "Second generation" diagnostic tests which test directly for the presence of the virus, namely HIV antigen tests and those based on recombinant DNA, need to be put on the fast track for licensure. The use of such tests by blood banks and other testing facilities would discount the "window" period during which antibodies have not yet appeared after a recent infection. Ongoing research into the further development, approval, and implementation of highly accurate and low cost HIV diagnostic tests needs to be prioritized.
- Those who manufacture and prescribe experimental drugs utilized under Treatment IND regulations are not protected from liability actions that may result from adverse drug reactions.

RECOMMENDATIONS

4-53 The team assigned to review the Investigational New Drug application should become involved with the product as early as possible and remain with the product through the New Drug Application approval. Their work should remain subject to independent Food and Drug Administration review.

4-54 The Food and Drug Administration should work with the National Institutes of Health and private drug companies to develop a software package which can be used to report and review data from preclinical and clinical trials, modified for each specific use, to shorten review time.

4-55 Information about which drugs are available under a treatment IND must be more widely disseminated. An information database must be created which should also offer information about potential toxicity as well as information about results of any clinical trials involving the drug.

4-56 If use of treatment INDs increases, the Food and Drug Administration's Commissioner should be given authority to monitor those drugs in Phase IV, after licensing is complete.

4-57 Treatment INDs should be used primarily by those patients who do not have access to experimental drug trials.

4-58 The Food and Drug Administration should fund an independent scientific organization to conduct an independent review of safety regulations dictated by the 1962 Kefauver Amendments to determine whether they should be relaxed for drugs used under Treatment IND regulations that are intended for terminally ill patients who have given informed consent.

4-59 In order to encourage the administration of drugs under treatment IND regulations, Congress should review current liability laws regarding these drugs and take appropriate action to extend liability protection to cover the manufacture and administration of these drugs.

4-60 The Food and Drug Administration should meet with industry representatives and the Commission on Rare Diseases to determine the most attractive package by which to both encourage additional research and development, and allow companies to provide orphan drugs at reasonable cost to patients.

4-61 Cost-effective methods, such as extension of market exclusivity, should be favored over those that require additional investment.

4-62 Professional pharmaceutical associations should survey members to determine what package of incentives would be most attractive to the producers.

4-63 Special track approval for medical foods, such as lipids, and especially those with long use in other diseases, should be considered.

4-64 Congress should immediately authorize and fund an additional 50 FTEs for the Food and Drug Administration's review of new drugs and vaccines.

4-65 The FTE level for reviewers should be tied to increases in the number of new IND applications.

4-66 Office and other support for these individuals should be given commensurate funding.

4-67 The Commissioner of the Food and Drug Administration (FDA) should develop a plan by which medical and other graduate education loans can be repaid through FDA service. Congress and the Administration should provide funds for this training program in FY 1989.

4-68 We urge the Food and Drug Administration to use deliberate haste in approving or rejecting the diagnostic products before them currently and in the developmental pipeline. Particular attention must be given to HIV antigen tests and any other new technology which tests directly for the virus. Consideration by FDA should be given to whether the review process could be expedited by moving regulatory control of HIV diagnostic tests from the Division of Blood and Blood Products to the Division of Medical Devices. We recommend increasing the pool of qualified individuals to staff the approval process by creating training grants in relevant departments of colleges and universities.

4-69 The Commission recommends the timely completion and release of ongoing Food and Drug Administration (FDA) studies on the efficacy and safety of condoms and surgical gloves in blocking transmission of HIV and recommends that these results be publicized by FDA. In addition, standards for condom safety should be increased, and studies should be conducted to determine the effects of spermicides, solvents, and other lubricants on latex. Studies to determine the shelf life of latex condoms, with or without lubricants or spermicides, should be performed, and packaging dated accordingly.

4-70 The federal government should provide funds for an additional office and laboratory building for the Food and Drug Administration's drug and vaccine application review personnel.

4-71 To inspire pride in the Food and Drug Administration (FDA), an annual Presidential Award for Excellence could be bestowed on dedicated FDA scientists who creatively and expeditiously approve life-saving products and discover ways to protect society from unforeseen health hazards.

Section IV. Clinical Trials: Testing Drugs in People

In HIV research, clinical trials (trials in humans) usually take place in medical centers or at the National Institutes of Health Clinical Center, and are funded by either the sponsoring pharmaceutical company, the federal government, or the two in combination.

The purpose of clinical trials is to determine the safety and effectiveness of a particular drug or vaccine with the greatest degree of certainty while testing the drug in the fewest number of people necessary to achieve this goal. This is because the drugs are experimental, and there is no guarantee that they will help the patient, and may in fact cause harm. Given the urgency of the HIV epidemic, there is the additional pressure to determine safety and efficacy as rapidly as possible.

Within the next few years, it is projected that there will be several hundred thousand persons with symptomatic HIV infection who will need treatment. The primary goal of current clinical trial programs is to develop drugs that can be safely used in these individuals, that will be effective in alleviating symptoms and, it is hoped, be effective in killing the virus and restoring proper immune function. In addition, trials in asymptomatic patients are also underway at NIH, to determine the effectiveness of drugs in delaying or preventing the onset of a symptomatic state.

In order to produce the quantities of drugs that are expected to be needed both now and in the coming years, more trials must be conducted immediately and conducted as efficiently as possible, to gain as much information as possible while conserving both time and human resources. The Commission endorses all efforts to ascertain that the participation of every individual in any clinical trial is valued and properly utilized, and that all trials be as beneficial as possible to both the participants and to the advancement of medical research.

Clinical trials are carried out in three phases, involving progressively larger numbers of people:

- Phase I trials are concerned primarily with learning more about the safety of the drug, though they may also provide information about effectiveness. They provide information on: how the drug is absorbed, metabolized, and excreted; what effect it has on various organs and tissues; and what side effects it has as doses are increased. Phase I testing is generally done on a small number of healthy volunteers. They are usually paid for their services, which essentially consist of submitting to a variety of tests to learn what happens to the drug in the human body. One of the chief causes of failure in this phase is evidence that the drug is toxic at doses too small to produce any beneficial effect.
- Phase II trials are designed to show whether the drug is effective in treating the condition for which it is intended. They also attempt to disclose short-term side effects and risks in people whose health is impaired. Most phase II trials are randomized controlled studies. Placebos are used when there is no historic or positive control available.
- Phase III testing is geared to developing information that will allow the drug to be marketed and used safely. Optimum dose rates and schedules are determined and, hopefully, any long-term side effects are revealed.

Study Design

Protocols must be designed to effectively gather large quantities of valuable information efficiently, to determine whether drugs work and are safe. The issue of placebo controls in clinical trials was raised by several witnesses. Currently, no new NIAID clinical trials in patients with life-threatening disease will be placebo-controlled, and, as more drugs show effectiveness, they may be added as positive controls to new drugs under study.

There are two classification systems currently in use to determine a patient's stage of disease: the CDC system (described in the Patient Care chapter), based on clinically apparent criteria, and the Walter Reed system, which additionally uses immune response parameters. Using a clinical staging system in research protocols encourages the use of clinical endpoints in trials, and this should be replaced by the use of immunologic criteria which can more precisely determine disease progression.

NIAID-funded HIV Trials

Clinical trials can be sponsored by private sector drug companies, or the federal government. Much of the drug development research done in the United States is conducted entirely in the private sector, and the pharmaceutical industry has a substantial history of developing and expertly managing clinical trials.

Federal funding for clinical trials for HIV-related illness is distributed through NIAID. In

1987, AIDS Treatment Evaluation Units (ATEUs) were established at the universities or medical centers originally designated to operate NIAID-sponsored HIV-related research. These centers have been renamed the AIDS Clinical Trials Group (ACTG). The recently redesigned program currently sponsors clinical trials throughout the country, with a total enrollment of nearly 4,000 patients, 800 on the NIH campus (intramural) and the remainder in participating clinical trial centers (extramural). To date, there are 35 funded institutions, 17 drugs in trial, 28 active protocols, and many new agents under study.

Initially, there was criticism that NIAID trials too often used AZT. When AZT was the only drug available with demonstrated efficacy, it was used in multiple trials in patients with a variety of disease manifestations in order to determine its range of usefulness. At present, AZT is being used in combination with other drugs, as well as singly with special patient populations.

Trials are underway with a large (1500) and increasing number of asymptomatic patients to determine if early treatment delays the onset of symptoms.

NIAID has convened an AIDS Program Advisory Committee which includes or will include representatives of affected minority communities, women, community health care providers, and social workers. Among its functions will be to determine whether the full range of the affected communities are represented in the clinical trial patient population, whether additional provisions need to be made to permit the sustained participation of these population groups in the clinical trial process (e.g., child care, transportation, additional primary medical care), and to assure that the data collected will be used to ensure that each patient's participation contributes to a scientifically valid and expertly managed trial. NIAID administrators have indicated a willingness to also include a qualified individual with HIV infection on this committee.

The Commission is concerned that with the number of new drugs under development, the number of additional clinical trials will soon escalate sharply, and the needed additional personnel will be unavailable. New personnel should be added and trained today. One witness suggested that in a national medical emergency, the NIAID clinical trials system could be supplemented by forming a consortium of smaller hospitals that could provide clinical trials resources. One principal investigator from one such smaller hospital, however, testified that internal difficulties within his institution had delayed start-up time of his trial by several months, which would slow overall progress for NIAID considerably. Another witness, a principal investigator in one of the earliest ATEU programs, suggested that to rapidly expand clinical trials, the Surgeon General could reassign commissioned officers in the Public Health Service to areas of the country in greatest need.

Research personnel also indicated that low salaries were a hindrance to hiring adequate numbers of trained nurses to staff the Clinical Center. On one ward, 100 personnel slots were authorized, approximately one-half of which were nursing slots. To date, only 11 of these positions have been filled. This has caused delays in implementation of clinical trial protocols. Salary structures for nurses have recently been modified, and similar modifications must be made for allied health care workers.

In the extramural trials funded by NIAID, an interesting working relationship has developed between centers funded to do studies, and some inner city hospitals with large HIV patient populations, which has led to complaints from these hospitals. Many municipal institutions lack a research infrastructure to support clinical trials at their hospital, but are asked to "lend" patients to medical centers funded for trials and then not included in either the administration of the study or reimbursed for their expenses. Equitable means of sharing the "intermediate cost recovery" (overhead payments) must be developed to encourage fair cooperation between institutions.

Pediatric Trials

One of the most pressing clinical trials needs is trials for pediatric patients. There are many unanswered questions in perinatology (the study of infants) that relate to HIV disease. What factors favor transmission from mothers to infants? What is the role of the placenta in viral transmission? Why do infants have earlier and more severe HIV infection? What is the role of breast feeding in transmission? How can transmission to fetus be identified early? Is treatment of pregnant mothers or newborn infants feasible?

The effects of HIV on the brain and, therefore, on the entire neurologic and neurodevelopmental systems of HIV-infected children are detrimental and profound. Of 30 symptomatic HIV-infected children under 15 months of age at the State University of New York (SUNY) Pediatric AIDS Clinic in Brooklyn, only 10 percent have normal mental and motor development.

There are no treatments for children with symptomatic HIV infection, and several obstacles prevent broad implementation of clinical trials. AZT, a drug that crosses the blood-brain barrier, and the primary drug proven effective against HIV, is not widely available to HIV-infected children. A placebo-controlled trial testing intravenous immunoglobulin recently opened that is expected to enroll 400 children. But this drug, which is not an anti-viral, does not address underlying HIV infection. In addition, many perinatally infected infants and children are "boarder babies" or wards of the state, and there are legal restrictions against their being entered into trials. Many of the metropolitan hospitals that have large pediatric populations with HIV infection have no research capability or staff to conduct trials.

Community-based Trials

Many witnesses before the Commission testified that there was a need for greater access by a broader spectrum of the infected population to clinical trials, specifically women, hemophiliacs, children, and transfusion-exposed individuals. Concern was expressed by many of these witnesses that drugs were being tested on one segment of the population and may be licensed for use in other segments without having been intensively tested in them. As these populations may represent the future of the epidemic (e.g., children and intravenous drug abusers), the immediate implementation of more broadly available therapeutic protocols is essential.

The Community Research Initiative (CRI) offers the possibility to combine the technical expertise of the research community with the outreach potential of community health clinics and physicians in community practice. This outreach effort to minority populations, drug users, and women may increase the access of these populations to experimental treatment. The Commission is hopeful that greater access by a broader based community will also increase the information gathered on co-factors and increase knowledge of disease manifestation and progression. In addition, as many "underground" drugs are being used by the HIV-infected population, community-based efforts may offer the added possibility of increasing our knowledge of the effectiveness of these substances, and how they interact with other medications. Such "observational trials" can also provide valuable information about "patterns of care" in community settings.

All protocols developed by CRI and other similar organizations that would follow, are prepared and screened by an Institutional Review Board (IRB), following the same procedure adhered to in medical research institutions. Individuals who are on the staff of such medical institutions are members of these boards and offer advice on scientific matters. All protocols offered to NIAID for funding will be passed by the IRB prior to submission, and ways are being studied to better link the work of CRI with the research establishment at NIH. NIAID has indicated a new clinical trial development strategy that will incorporate greater community participation.

A model community physician training program was developed by NCI in the 1970's, and could be useful in developing a similar one for HIV clinical trials. The program, known as the Community Clinical Oncology Program, provides a training base for physicians in community practice, who come to major research centers to acquire the latest research information and clinical trial management skills. A similar program could be developed within the infectious disease departments of major centers already in the ACTG program, to train physicians who work with currently underserved populations.

Obstacles to Progress

- As the number of new drugs developed increases, the number of clinical trials will increase, and more staff will be needed at NIAID to manage them.

- Community-based physicians are not currently involved enough in the clinical trial system. This is an underutilization of valuable resources.

- A broader spectrum of individuals needs to become involved in clinical trials in order to ensure safety and efficacy of approved drugs in all patient populations.

- Those who need clinical trial information most -- doctors and patients -- usually do not know how to get it or are unable to do so.

- Therapeutic trials for infected infants and children do not exist in adequate numbers, and there are not enough actual or planned NIAID Clinical Trials Centers for pediatric trials.

- Personnel shortages at the NIH Clinical Center are slowing the implementation of drug trials.

- There is no program similar to the Community Clinical Oncology Program to train community-based investigators in HIV clinical research.

RECOMMENDATIONS

NIAID Clinical Trials and Studies

4–72 Membership in the National Institute of Allergy and Infectious Diseases' AIDS Program Advisory Committee should include at least one qualified individual with HIV infection. Members should also include representative minorities, parents of HIV-infected children, women, and hemophiliacs.

4–73 The National Institute of Allergy and Infectious Diseases should develop means by which clinical trials can be made available to individuals in all geographic areas of the country.

4–74 To better understand the natural history of HIV-infection in women, the National Institute of Allergy and Infectious Diseases should fund female cohort studies and enroll women in different stages of HIV-related illness.

Clinical Trial Information Registry

4–75 Registration of all HIV-related clinical trials information, and information on approved substances and INDs should be made available in one central location. If it is modeled after the Physician's Data Query System in the National Library of Medicine, software must be developed to make the retrieval of hard copy information possible.

4–76 Information regarding the nature and status of clinical trials should be readily accessible to all interested parties in this country and to central health agencies in other countries.

4–77 The NIH Office for AIDS Research should assume responsibility for developing an appropriate, quality-assured database for collection and distribution of this information, and should have it operational no later than December 31, 1988.

4–78 All trials should be registered by the sponsor within seven days of approval by the Food and Drug Administration. The sponsor should furnish complete protocol information including but not limited to the drug(s) being tested, inclusion and exclusion criteria, pertinent drug-taking restrictions, trial site(s), the names of principal investigators with contact information, and trial commencement and termination dates.

4–79 The clinical trials database must be constantly updated and must include information on trials conducted by the National Institutes of Health, and by private pharmaceutical companies, and must, as soon as possible, include trials conducted in other countries. Patient enrollment information must also be updated.

4–80 If the Physician Data Query System is selected and used in conjunction with the Centers for Disease Control (CDC) Clearinghouse, a public information campaign should be authorized. Health and science editors of all major media should be made aware of existence of the system to make it more widely understood by physicians and patients alike. This should be done by cooperative agreement between CDC, the National Cancer Institute, and the National Institute of Allergy and Infectious Diseases, with additional funds made available.

Study Design and Implementation

4–81 Use placebo-controlled studies only for patients without immediately life-threatening disease, and positive control studies in patients with symptomatic HIV infection.

4–82 In the process of giving informed consent for participation in a clinical trial, the participant should fully understand all aspects of the study and commit to faithful adherence to the protocols.

4–83 To more effectively analyze information across multiple trials, standardize staging criteria and utilize the Walter Reed staging system to establish disease stage and clinical trial endpoints.

4–84 In order to accelerate evaluation of efficacy of a new drug, reevaluate the endpoints of current clinical trials to determine whether markers other than clinical morbidity or mortality (e.g., laboratory markers) can be used.

4-85 Develop means of shortening the time frame of Phase II trials, perhaps by increasing sample size or changing the endpoints.

4-86 Establish as a high priority the development of trials with sufficient numbers of women (including pregnant women), infants and children, hemophiliacs, transfusion-infected individuals, and intravenous drug users to both serve these populations and be statistically evaluable.

4-87 Prior to the initiation of all new HIV-related trials, the National Institute of Allergy and Infectious Diseases should require a commitment on the part of participating institutions to rapid and active facilitation by their Institutional Review Boards and other internal regulatory mechanisms so that protocols are rapidly implemented.

Data Collection

4-88 The federal government should immediately fund a pilot study for the development of computer software that could be used across all HIV clinical trials to standardize clinical data input and facilitate the rapid evaluation of those trials by the Food and Drug Administration (FDA). This pilot study should include experts from the computer support divisions of FDA and the National Institutes of Health, as well as clinical and review experts.

4-89 This software should be immediately used to begin collecting co-factor information on ongoing clinical trial participants.

4-90 Information gathered on placebo recipients should be used to formulate the equivalent of a "historic control" for HIV so that future studies can be designed with decreased reliance on placebos as controls.

Pediatric Trials

4-91 National Institute of Allergy and Infectious Diseases Clinical Trials Centers for children should be expanded from the presently planned three to six to 20 throughout the United States.

4-92 All clinical trials developed for adults at the National Institutes of Health should also address the possibility of being utilized in pediatric populations, wherever possible in the form of a "concept proposal."

4-93 Because of the high percentage of HIV-infected children who suffer severe neuropathy, drugs that cross the blood-brain barrier should be given highest priority in the design and implementation of clinical trials for this population. Protocols for every trial should include neurologic and neurodevelopmental tests to determine the neurologic efficacy or toxicity of the drug.

4-94 In order to facilitate patient accrual in pediatric trials and deliver experimental treatment and superior care where it is most needed, clinical facilities in areas with high prevalence of pediatric infection must be upgraded so they can conduct more demanding Phase I and Phase II trials; these facilities must be given the means to recruit the personnel necessary to conduct these trials.

4-95 Wherever legal restrictions bar the entry of "boarder babies" and other foster children into clinical trials, these restrictions must be examined and challenged as appropriate, to make certain that these children are not being denied access to palliative or possibly curative therapies.

Community-Based Trials

4-96 Activities already in progress at the National Institute of Allergy and Infectious Diseases should be encouraged to incorporate greater participation of industry and community physicians in protocol development and implementation.

4-97 A direct grant program should be funded immediately to assist community-based trial sponsors to develop and implement clinical trial protocols, and to encourage increased access to these protocols by any underserved populations.

4-98 The National Institutes of Health Office for AIDS Research should develop a training program for community practice physicians whereby physicians can acquire both the latest HIV research information and clinical trial management skills. This program could be patterned after the Community Clinical Oncology Program, should be funded through existing AIDS Clinical Trials Group centers, and should be designed to develop a broader base of clinical expertise for administering HIV-related clinical protocols as they become available. Funds for this program should be made available in FY 1989.

4-99 Community-based organizations and community health centers should be consulted in the design and should be used in the execution of clinical trials.

4-100 Community-based trial investigators should be encouraged to work closely with leading clinical researchers and basic scientists at medical institutions in their community to establish better research relationships and provide the best service to their patients.

Section V: Additional Research Needs

Behavioral and Social Science Research

HIV transmission is linked to specific and potentially changeable patterns of behavior. For individuals currently engaging in those behaviors, prevention of transmission depends on implementing effective behavioral change programs which seek to reduce or eliminate exposure to the virus. Research on sexual and drug-abusing behavior must, therefore, be an integral part of all HIV intervention efforts.

The study of human behavior is a complex endeavor which includes a variety of disciplines with numerous methodologies. The need to change individual behavior and to sustain that change will be paramount indefinitely. Given the central role of behavioral and social processes in the HIV epidemic, it is essential that the social and behavioral sciences be given priority in the funding portfolios of the appropriate Public Health Service agencies (Alcohol, Drug Abuse and Mental Health Administration and the National Institutes of Health).

Evaluative components must be built into any intervention program to determine which elements of the program were successful and which were not. The incorporation of evaluation into such programs is often far from ideal, not only for financial reasons. The forging of a relationship between researchers and members of community projects who may be suspicious of the intentions of researchers is difficult at best. Yet evaluation of programs by trained researchers remains the only way to determine program success.

To date, most of the efforts used to stop the spread of HIV have been informational mass communications, such as pamphlets, public service announcements, advertisements in magazines, and -- to a limited extent -- television commercials. However, some behavioral research indicates that simply providing information may increase awareness about HIV, but does not necessarily lead to change in risk behavior.

Sexual Behavior

Transmission of HIV can occur in any sexual behavior (from female to male, from male to female, and between two partners of the same sex) in which there is an exposure of HIV-infected body fluids to cells which can be infected. For this reason, research on sexual behavior is particularly relevant for designing and implementing appropriate and effective prevention programs. In addition, research indicates that sexual behavior and attitude vary somewhat as a function of ethnicity and culture. In order to be effective, educational efforts must be sensitive to these differences.

A behavioral model that has been tested in terms of sexual behavior change in response to the HIV epidemic is the Health Belief Model which states that risk reduction depends on knowledge about HIV, a sense of perceived risk, a sense of personal efficacy (i.e., a feeling of having the mechanical and social skills necessary to make changes), and a perception that community norms support HIV risk reduction.

One area of concern in behavior change, illustrated by the study of human sexuality, is relapse prevention. Maintenance of behavior change is often perceived to be more difficult than the original change itself. Among other areas of concern are: the seeming inability of some individuals to enjoy and maintain exclusive sexual relationships, and those individuals whose behaviors may pose an increased risk of HIV transmission -- including those diagnosed by sex therapists as sexually compulsive, hypersexual, or sexually addicted.

Currently, researchers in the field of adult sexual behavior must continue to refer to data collected by Kinsey over 40 years ago. There is an urgent need to update the information base. Data collected in the future should include not only prevalence of behaviors, but also attitudes and beliefs about sex.

Research areas which need attention are not limited to the behavioral area. Some are interpersonal in nature (e.g., developing assertiveness to resist coercion by partners to engage in high-risk sex and developing social skills to maintain stable relationships). Therefore, it is important to support a variety of programs that reflect different approaches to behavior change (e.g., programs that emphasize acquisition of skills, the changing of norms, and intensive counseling).

Behavior Studies in Homosexual and Bisexual Men

There is reason to be optimistic about projects aimed at reducing high-risk behaviors. Results from a behavioral research study in San Francisco shows that the incidence of detected HIV infection in a group of over 800 homosexual and bisexual men is approaching zero. From 1984 through 1986, the prevalence of HIV-infection in this group of homosexual and bisexual men was stable at approximately 50 percent. Not surprisingly, this is concomitant with substantial reductions in self-reported high-risk activities. The study results may show effectiveness in both behavior modification efforts and community-based HIV educational programs.

There are some researchers who believe that the San Francisco study sample is not representative of all homosexual and bisexual men. Therefore, further studies must be targeted on this population.

Behavior Studies in Women

In general, HIV service programs and educational efforts have not taken into account women's social roles, childbearing and child care responsibilities, or their economic position relative to men. There is considerable interest in women in HIV research as vectors of transmission as mothers or prostitutes. However, there is a general lack of information in HIV literature on the psychosocial problems of women as they cope with illness.

The greatest number of diagnosed AIDS cases among women occur in the black and Hispanic population. Approximately 51 percent of all AIDS cases in women are among black women and 20 percent are among Hispanic women. Thus, there are ethnic and cultural issues that are important areas of research for women with HIV infection. Qualitative research is also needed on why women may choose to get pregnant and bear children even though they know they are infected with HIV and have approximately a 50 percent chance of infecting their child.

Adolescents

The Commission believes there should be more extensive behavioral research on adolescents. Although adolescents currently represent a relatively small percentage of all reported AIDS cases (approximately one percent), the potential exists for a significant increase in this percentage. As of January 1988, over 700 cases of AIDS were reported to the Centers for Disease Control in the 13 to 21 year old age group, and this number is doubling each year. Estimates show that about 20 percent of all persons with AIDS are in their twenties. However, because of the long latency from infection to onset of disease symptoms, many of the cases of AIDS detected in young adults developed in all likelihood from infection with HIV in adolescence. According to preliminary Army data, during the first two years of the military screening program, 673,031 teenage youths, ages 17 to 19, were tested. Overall, 226 teenage applicants were found to be seropositive (0.034 percent). However, this preliminary data showed the prevalence rate among female military applicants age 17 was 0.032 percent, twice that of male applicants age 17 (0.015 percent).

Estimates vary widely on the proportion of adolescents who are sexually active, ranging anywhere from 50 to 70 percent. Evidence suggests there is a greater number of adolescents engaging in sexual activity at progressively younger ages.

But the threat of HIV transmission in adolescents is not limited to sexual activity. The urgent necessity of addressing the special needs of adolescents is nowhere more poignant than on the streets of America's major cities where runaways often migrate. Many runaway and homeless adolescents are caught at the juncture of risks that include sex and drugs. Both male and female adolescents often use prostitution as a means of supporting themselves and possibly a drug habit. For example, in a small study conducted at the Covenant House, a shelter for runaway youth in New York City, approximately 40 percent of the adolescents were HIV-infected.

But activities that increase the risk of HIV infection are not limited to runaway and homeless adolescents. For example, one percent of high school seniors surveyed reported having used heroin intravenously.

Several studies in the San Francisco area have brought to light misperceptions among adolescents concerning routes of transmission, modes of effective prevention, and information about HIV. These misperceptions significantly contribute to their behavioral risk of HIV infection. For example, one study showed that adolescents tend to overestimate the risk of contracting HIV through casual contact, but more importantly they tend to significantly underestimate their risk of contracting the virus through sexual contact. Another study revealed that white high school adolescents were more knowledgeable than black adolescents about all aspects of HIV. In the same study, less knowledge was associated with an increased perceived risk of contracting HIV. Prevention programs for adolescents should promote changes in attitudes toward risk behavior as well as increasing awareness about risk and emphasize the benefits of behavior change.

Educators, or those who counsel or provide information to adolescents, must appear credible. Research on adolescents shows that peers tend to be a predominant source of information about sexuality and have a strong influence on sexual behavior. Education in non-traditional, peer settings has been found effective.

Federal Research Efforts

The National Institute for Mental Health (NIMH), within the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), is the focal point within the federal government for research on behavior and its psychological and psychosocial determinants. NIMH supports research and research training in the biological, psychological, epidemiological, and social science aspects of mental health and illness.

The National Institute on Drug Abuse (NIDA), another ADAMHA institute, conducts research to improve the effectiveness of drug abuse treatments and behavior change strategies in order to prevent drug use and to prevent the progression from non-intravenous to intravenous drug use.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) will be funding research on the relationship of alcohol-related behaviors that increase the risk of transmission of HIV and strategies to prevent that risk.

The National Institute of Child Health and Human Development (NICHD), within NIH, currently has a smaller behavioral research program involved in developing and testing interventions to prevent the spread of HIV among sexually active adolescents and other high-risk populations. In addition, NICHD will be conducting research on general sexual attitudes and behaviors and on pediatric and adolescent HIV issues.

CDC collaborated on some of the earliest behavior research related to the HIV epidemic with its cohort studies of homosexual men in San Francisco. It currently funds several demonstration projects focusing on the effects of community-based interventions to stimulate changes in knowledge, attitudes, and behaviors and is contributing to the Public Health Service (PHS) survey research efforts.

Much of this work is complemented by a foundation of health-related behavioral research conducted through other PHS agencies. For example, principles of behavior change (such as those used in research sponsored by the National Cancer Institute in smoking cessation programs and the National Heart, Lung, and Blood Institute in its cardiovascular community intervention trials) are directly applicable to changing risk behaviors associated with HIV transmission.

Federal funding for behavioral research flows primarily through NIMH. However, behavioral change research has received inadequate priority in funding in the past decade. The National Academy of Sciences has stated in *Confronting AIDS* that "the knowledge base in the behavioral and social sciences needed to design approaches to encourage behavioral change is more rudimentary because of chronic inadequate funding."

Research must continue into determinants of high-risk behaviors and the development, implementation, and evaluation of culturally specific risk reduction and risk elimination programs designed to prevent further spread of HIV.

The success of preventive intervention programs depends upon an informed understanding of health behaviors and the determinants of behavioral change. HIV research requires a multidisciplinary perspective. Experts of different disciplines within the behavioral and social sciences do not always sufficiently collaborate among themselves as well as with other disciplines in the biomedical sciences, though there are current efforts to increase collaboration, such as the Committee on Behavioral, Social, and Statistical Sciences of the National Academy of Sciences. Social and behavioral research in HIV must be long-term, collaborative efforts such as that found in the NIMH Centers Program grant mechanism.

The NIMH Centers are multidisciplinary and multi-institutional operations. They support basic, clinical and applied research, and prevention and educational research. All Centers contain information dissemination components, and each maintains contacts with community groups for access to high-risk populations. It is imperative that this mechanism for funding research be maintained and funding expanded, particularly for behavioral and social sciences research.

Obstacles to Progress

The Commission has identified the following obstacles to progress in the behavioral and social science research area:

- Social and behavioral research has been underfunded and undervalued as a tool for developing effective prevention programs.
- Better coordination and collaboration are needed among PHS agencies regarding their behavioral research activities.
- Significant data are lacking on the sexual behavior patterns of adults and young people of varying ages and cultural backgrounds.
- Often, prevention programs are not successful because of insufficient collaboration among service providers and behavioral researchers.
- Researchers are not given enough time to evaluate the effectiveness of programs and once a strategy is found effective, the means are lacking for widespread dissemination of that finding.
- Parents and educators often disagree on the context and format of school-based sex education. Some fear that sex education will encourage sexual experimentation in adolescents while others believe sex education is essential to prevention.
- HIV prevention programs are not sufficiently comprehensive, lacking research-proven behavior modification components in providing options for individuals attempting change.

RECOMMENDATIONS

In response to these obstacles, the Commission recommends the following:

4–101 The Department of Health and Human Services, through the Alcohol, Drug Abuse, and Mental Health Administration, the National Institutes of Health, and the Centers for Disease Control should continue and expand the funding of research on adults *and* adolescents that identify: determinants of risk behavior; models of behavior change interventions (in laboratory, field, and community-based settings); social factors and strategies to affect behavior change; and evaluation and other methodologies.

4–102 All HIV-related research funded by the National Institute of Allergy and Infectious Diseases and the National Institute of Mental Health should be reported to a central information gathering source. In the HIV crisis, data sharing should be the rule.

4–103 Funds should be made available through the National Institute of Mental Health and the Centers for Disease Control to sponsor training programs for graduate and post-graduate HIV researchers in the field of behavioral research.

4–104 Funds should be allocated for training grants for pre- and post-doctoral students in academic settings for research in the disciplines related to HIV research such as psychoimmunology, social psychology, human sexuality (including bisexuality), and behavioral sciences.

4–105 Social and behavioral research in HIV must be long-term, collaborative efforts such as that found in the National Institute of Mental Health Centers Program grant mechanism. It is imperative that this mechanism for funding research be maintained and increased in behavioral and social sciences research and that the Centers continue to play a significant role in behavioral and social research.

4–106 The Department of Health and Human Services, through the National Institutes of Health, the Centers for Disease Control (CDC), and the Alcohol, Drug Abuse and Mental Health Administration should take advantage of work already begun by the National Institute of Child Health and Human Development, in collaboration with CDC, and continue to fund national baseline data collection activities with longitudinal components, that would permit a better understanding of sexual practices (including bisexual behavior), attitudes, and risk behaviors of adults *and* adolescents of differing ages and cultural backgrounds in order to assess risks and guide intervention activities. Survey research should include proportionate sampling of ethnic, racial, and cultural groups, and regional variations.

4–107 The Department of Health and Human Services, through the National Institutes of Health, the Centers for Disease Control, and the Alcohol, Drug Abuse and Mental Health Administration, should fund small-scale surveys and studies in targeted groups to identify attitudes and behaviors that should be modified or reinforced prior to development of education programs or other interventions that will be effective in those target groups and the cost-effectiveness and efficacy of various channels for reaching such groups.

4–108 The National Institute of Mental Health's review panels ("study sections") which determine which grants are approved and given priority scores for funding should maintain a sufficient balance and expertise in the area of behavior change research.

4–109 The National Institute of Mental Health in collaboration with other Public Health Service agencies should continue to fund research to assess the impact of learning the diagnosis of HIV infection on individual behavior, and whether the impact varies by risk group.

4–110 A working group on HIV infection and adolescents should be established through expansion of the mission of the Department of Health and Human Services' Pediatric AIDS Working Group.

4–111 The National Institute of Mental Health, in collaboration with the National Institute on Drug Abuse, should conduct studies of the determinants of the point of entry that puts an individual at risk and patterns of drug use and sexual practices (particularly, bisexual practices).

4–112 Researchers must be given sufficient time to evaluate the effectiveness of programs, and once found effective, be given the means for widespread dissemination of those findings.

Co-Factors

Co-factors are those conditions or influences which, when present or absent, influence individual susceptibility to infection and disease progression.

Biomedical researchers interested in the study of co-factors in HIV infection have included the following in their study: presence and history of other sexually transmitted diseases; presence of other infections; pregnancy; behavioral factors; nutritional factors; and psychosocial factors (such as stress) that influence the immune system.

In addition to these, co-factors which influence risk behavior need to be considered. Such factors are individual perception of risk, belief in the efficacy of behavioral change, and the norms which either support or sanction risk behavior.

Alcohol and substance use represents both a risk for initial infection and a possible co-factor in disease progression. The disinhibitory (judgment impairing) effect on behavior of alcohol and drugs makes use of these substances a potential risk factor for HIV infection. There is also some evidence to suggest that alcohol and certain drugs may have an immunosuppressive effect, possibly hastening progression of disease.

Research investigating co-factors is being conducted under the auspices of various PHS agencies along a continuum of intervention efforts. Research in these areas can be used to design programs which may prevent initial HIV infection, prevent the onset of symptoms in HIV-infected individuals, and ameliorate symptoms in persons already symptomatic. There is some concern over a lack of coordination among these agencies. Because of the multidisciplinary nature of HIV research, close communication is needed across federal agencies and disciplines, both intramurally and extramurally.

Obstacles to Progress

- Co-factor studies, which examine the effects of previous histories of other sexually transmitted diseases, the presence of other infections, pregnancy, nutritional, behavioral, and psychosocial factors, have been underfunded.
- Other co-factor research on factors influencing behavioral risk has also been underfunded.
- A lack of coordination among appropriate PHS agencies may act to slow the progress of research in this area.

RECOMMENDATIONS

In response to these obstacles to co-factor research, the Commission recommends the following:

4–113 The National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration should ensure that there is sufficient coordination and collaboration in research in the areas of neurosciences and neurobiology to avoid duplication of research efforts. This recommendation is not intended to reduce funding of confirmatory studies.

4-114 The Department of Health and Human Services, through the National Institute of Child Health and Human Development, the National Institute of Mental Health, and the National Institute on Drug Abuse, should fund a cohort study to determine the natural history of HIV infection in women and special social factors related to women at risk for HIV infection.

4-115 Funds should be made available through the National Institute of Mental Health and the Centers for Disease Control to sponsor training programs for graduate and post-graduate HIV researchers in the area of co-factors associated with onset and progression of HIV-related diseases.

4-116 The National Institute of Mental Health should continue to support research on the neurobiological and psychobiological processes, and the behavioral, psychosocial, and psychiatric factors thought to be associated with both the transmission of HIV infection and the progression of disease.

4-117 The National Institute of Mental Health (NIMH) should issue a competitive request for proposal to establish a center where researchers from various disciplines could convene to exchange information formally and offer training in their discipline to researchers interested in integrating ideas. As the study of HIV co-factors is multidisciplinary, there should be cooperation between NIMH and appropriate agencies whose work is also devoted to concerns surrounding intravenous and other drug abuse.

4-118 The appropriate Public Health Service agencies should continue to fund neuropsychiatric research on symptomatic and asymptomatic HIV-infected patients. Research is needed to improve current testing instruments and methods of neuropsychiatric diagnostic testing for central nervous system involvement.

4-119 The National Institute of Mental Health should continue to conduct research with the National Institute on Drug Abuse and the National Institute of Alcohol Abuse and Alcoholism to better understand the impact of affective states, social isolation, and disinhibitors, such as alcohol and drugs on risk behaviors.

Transmission

Continued and expanded research is needed in the area of HIV transmission. The Multi-Center AIDS Cohort Study (MACS), funded by NIAID, is currently studying homosexual and bisexual men over time to gather transmission and other data.

While the MACS project must continue, similar studies must be funded to determine these factors in other populations at risk, especially female partners of infected men, intravenous drug abusers, and both heterosexual and homosexual adolescents. Data are needed on the efficiency of transmission from male to female, female to male, and between two partners of the same sex in which there is an exchange of HIV-infected body fluids.

Perinatal transmission is not well understood. It is still unclear why some babies of HIV-infected mothers develop HIV infection and some do not. Possible routes of perinatal transmission include transplacentally, during the birth process, and after birth through breast feeding.

Obstacle to Progress

- There is a lack of sufficient information regarding the effectiveness of transmission through different routes. This not only makes risk assessment difficult, but makes it more difficult to determine which programs would be most effective in halting the spread of the virus.

RECOMMENDATIONS

In order to further efforts in this area, the Commission recommends:

4-120 Funds should be made available through the National Institute of Mental Health, the National Institute of Child Health and Human Development, and the Centers for Disease Control to sponsor training programs for graduate and post-graduate HIV researchers in the area of HIV transmission and maternal, perinatal, and neonatal HIV infection.

4-121 Research should be expanded to include studies to determine the effectiveness of viral transmission through various routes such as intravenous drug abuse, various modes of sexual activity, and perinatal transmission.

CHAPTER FIVE: THE PUBLIC HEALTH SYSTEM

The HIV epidemic has presented a tremendous challenge to this nation's public health and education systems. The preventive response to the epidemic must be multidisciplinary, involving the public health community, the traditional education community, private and public health care providers, and substantial involvement of private, voluntary initiatives. The response must also be flexible and creative, not bound to a single approach.

The public health system, a system which has been fighting disease and promoting the general health of our nation's population for more than a century, has the primary responsibility to provide leadership in the design and implementation of strategies intended to halt the spread of HIV. The public health system cannot, however, lead in a vacuum. It must actively seek participation and cooperation from individuals who have in the past been considered outside that system. Prevention and education strategies that are not coordinated and that do not include input from all sectors of society will not succeed.

The basic legal framework of the public health system is the public health laws of the states and territories which give authority for the protection, preservation, and promotion of the health of the population. The federal government, through the Public Health Service (PHS), has the responsibility for protecting the nation as a whole and for coordinating among and providing technical assistance to the state and local agencies. Local public health agencies (city and county) act under local ordinance or a delegation of state law to serve a more limited geographic area. National efforts, such as the universal reporting of syphilis and rabies, are carried out by the voluntary coordination of the states and territories working through local agencies and in collaboration with the key federal agency, the Centers for Disease Control (CDC).

Section I. The Federal Role

While many branches of PHS contribute to prevention, CDC is the lead agency in this endeavor. The Epidemic Intelligence Service was created within CDC in the 1950s to provide a highly trained and mobile work force which could be quickly deployed to investigate a public health emergency. CDC is charged with: preventing and controlling infectious and chronic diseases; preventing disease, disability, and death associated with the environment and the workplace; and reducing health risks through education and information. All of these are done in partnership with state and local health agencies.

CDC began its AIDS efforts in the spring of 1981 by conducting epidemiologic and laboratory investigations to determine the cause and document the epidemiologic trends. The use of a nationwide communications network alerted all states to the epidemic in 1981 and encouraged state and local interest in the new condition. Some members of the Epidemic Intelligence Service as well as other CDC employees were diverted from their regular duties into a variety of special projects designed to better understand this new disease. The following year, CDC provided New York City with federal funds for its surveillance program. In 1983, additional funds were provided by CDC to states and cities that had the largest number of AIDS cases. 1983 also marked the year that CDC, in conjunction with state epidemiologists, determined that AIDS should become a reportable condition, and appropriate instructions were issued by every state. In 1985, CDC began allocating funds to state and local public health departments for AIDS information and education initiatives. Counseling and testing programs became part of CDC's funding agenda in 1986. No funds for overall program management were included. CDC's education plan further expanded in 1987 with the establishment of the National Aids Information and Education Program Office, whose purpose is to provide mechanisms that will educate and inform the public. CDC's planned HIV activities for 1988 include an AIDS information mailer that was sent to every American household in May and June, the establishment of a clearinghouse that will serve as a reference center where the public may obtain information concerning the HIV epidemic, and further expansion of surveillance activities.

A critical role of CDC is its leadership for state policy design and its collaboration with state public health agencies in surveillance. Although CDC's definition of AIDS originally defined the problem well as it was early understood and assisted scientific and public understanding as well as originally possible, CDC has lagged behind scientific understanding by not moving to an HIV infection-based data collection system when the antibody test was developed in 1985 to detect infection in asymptomatic persons. It is critical that CDC work with the states to collect HIV infection data and end its focus on symptomatic disease.

CDC's HIV efforts have illustrated the agency's strengths and weaknesses that must be discussed in defining CDC's role in combating the HIV epidemic. The areas to be examined include: CDC's budget; its structural organization; its personnel; its location; and its AIDS education and information programs.

Section II. The CDC Budget

Since 1981, CDC's AIDS budget has significantly increased from $200,000 to approximately $305 million in FY 1988. Today, AIDS represents 40 percent of the CDC budget. During this same time period, very few CDC programs have realized as much growth as its AIDS activities.

Obstacles to Progress

In order for CDC to expand its prevention efforts, the following obstacles must be overcome:

- Prevention programs are budgeted via annual appropriations, while federal illness treatment programs are entitlements that allow continued access to funds. This limits the ability to plan programs over long periods of time, though most prevention efforts must be multi-year and will not have "pay-off" in reduced mortality or morbidity during the first 12 to 24 months of program activity. For example, there are no entitlements for immunization for all children in the United States. There are just year-to-year dollars eroded by inflation. On the other hand, annual appropriations maintain the opportunity for oversight and accountability.

- There is a lack of sufficient funds for many CDC programs. CDC's overall budget has received only slight increases in recent years. For the most part, these increases occurred within the HIV budget, while the other CDC programs have basically remained level funded or have been tapped to augment HIV needs. A key example that illustrates CDC's budgeting constraints is its funding allocation for sexually transmitted diseases (STDs) other than HIV. For FY 1988, the federal government has allocated $65 million for STDs (this does not include funding for HIV). For FY 1989, the President's budget request includes less than a $300,000 increase for the STD program. While the budget request accounts for little more than inflation in funding STD activities, a resurgence in STDs is apparent in many parts of the nation. From 1986 to 1987, infectious syphilis cases rose 30 percent. The HIV epidemic has had an adverse impact on the availability of senior scientists and public health advisers for STD investigation and control.

RECOMMENDATIONS

5-1 The Department of Health and Human Services should propose and Congress should support mechanisms to sustain longer term commitments to prevention programming than are now the case. Such mechanisms must include annual accountability for programs and regular evaluation of the effects of prevention services.

5-2 Without reducing funds for other prevention activities under the Centers for Disease Control's (CDC) jurisdiction, appropriations to CDC should include not only funds for direct activities and pass-through allocations to state and local governments, but also funds for the management and evaluation of HIV-related activities.

5-3 Sexually transmitted diseases (STDs) are believed to be a significant co-factor of HIV infection. Recognizing this relationship, the Centers for Disease Control should significantly increase its FY 1989 funding for STD programs.

Section III. CDC Management

HIV prevention activities in CDC are distributed through eight entities. These are: the Office of the Deputy Director for AIDS, which supervises all of CDC's HIV activities; the National AIDS Information and Education Program, which disseminates information to the public; the Center for Infectious Diseases, which is in charge of surveillance, epidemiology, and laboratory science; the Center for Prevention Services, which handles target groups, health education, and risk reduction; the Center for Health Promotion and Education, which administers the school health education program; the National Institute for Occupational Safety and Health, which examines HIV in the workplace; the Training and Laboratory Program Office, which handles laboratory evaluation and training; and the National Center for Health Statistics, which conducts health interview surveys. In order for CDC's HIV programs to succeed, it is crucial that the eight offices involved with HIV programs interact frequently and coordinate their efforts and that the agency shift focus to include the full spectrum of HIV disease.

Obstacles to Progress

- The "matrix management" model, which has most HIV personnel reporting their activities in a line to both a major subunit of CDC and to the Deputy Director for AIDS, is confusing. Persons seeking information and assistance from CDC may not find it quickly. Activities in one area may not be coordinated with related activities in another center.
- Continued use of the term "AIDS" rather than "HIV" in program titles and written materials contributes to the national confusion regarding this disease.
- The continued CDC focus on AIDS case reporting is blocking efforts to track the epidemic and to plan, target, and implement prevention strategies and is misleading the public as to the urgency of the problem.

RECOMMENDATIONS

5-4 The Centers for Disease Control (CDC) should design and immediately implement an internal plan for coordinating all of their HIV-related efforts. This task should be completed by September 30, 1988. Such a plan should specifically state the responsibilities of all CDC units that are involved in HIV programs. It should also outline the coordination and communication processes between all participating CDC entities.

5-5 The Centers for Disease Control (CDC) should establish by August 1, 1988, a clear and comprehensive mission statement for the Office of the Deputy Director for AIDS. This statement should include the specific duties for that office as well as how that office will relate to all divisions of CDC.

5-6 The Centers for Disease Control should immediately emphasize its focus on the HIV disease, collecting data beginning at infection.

Section IV. National AIDS Information and Education Program

The National AIDS Information and Education Program (NAIEP) was established in April 1987. Its purpose is to provide a focus for CDC's public information and education endeavors related to the HIV epidemic. NAIEP is intended to serve as a link to national and community-based organizations that are essential in providing comprehensive HIV information and education.

For its first year of operation, NAIEP operated on a budget of $23.6 million. Its budget for 1988 is slightly over $41 million. NAIEP's activities include:

- direction of the National AIDS Information Campaign. The information campaign is a media-based public information effort intended to relay to the public facts about HIV. The contract for the campaign was awarded to a large public relations firm. Some of the campaign's activities include public service announcements and a national mailing to every American household regarding HIV. The campaign's goal is to positively influence the public's knowledge and attitudes concerning HIV. The contract is presently funded at $7.9 million with several outstanding change orders. The estimated cost of these modifications is $1.4 million.
- direction of the National AIDS Clearinghouse. The clearinghouse is also operated through a contract with a private organization. It is intended to serve as a resource center for materials discussing AIDS and HIV infection. For FY 1988, the clearinghouse is funded at $2.2 million.

- direction of the National AIDS Hotline. The hotline is also operated through a contract. Since the awarding of the contract in 1986, the hotline has been funded at $8.5 million.
- funding of minority outreach programs. Currently NAIEP administers the Minority Outreach Program which, through grants and contracts, is intended to assist national and regional organizations in developing minority initiatives that will target HIV information to minority populations. Funding for minority initiatives for FY 1988 is $19.5 million.

The NAIEP office must not only serve as a facilitator, but also as a coordinator for information and education programs. After one year of existence, it appears that there are several obstacles blocking NAIEP's path to functioning effectively.

Obstacles to Progress

- After more than one year of existence, this office has yet to determine its goals. A cohesive plan of action and sense of mission is lacking. NAIEP has contracted with a private organization for the purpose of developing its own goals and objectives.
- There is an absence of communication among the various CDC entities regarding CDC's HIV activities and programs. This has resulted in a lack of coordination regarding a national HIV prevention and education plan.
- NAIEP has contracted out the majority of its significant activities. Because of the limited number of full-time equivalent staff positions (FTEs) and the lack of direction and coordination within NAIEP, there has been limited and sometimes inconsistent guidance from CDC regarding contract implementation and oversight.

RECOMMENDATIONS

5-7 The Centers for Disease Control should devise its own program goals and objectives, and should not enter into contracts with outside consultants for this purpose.

5-8 The Centers for Disease Control should move the National AIDS Information and Education Program (NAIEP) to the Center for Prevention Services by September 30, 1988. This will avoid any duplication of activities that is presently occurring between NAIEP and the Center for Prevention Services.

Section V. CDC Personnel and Infrastructure

From FY 1981 through FY 1988, a total of 165 new personnel positions (FTEs) were added to CDC for HIV activities. For FY 1988, CDC has 416 FTEs assigned to HIV initiatives. Of this total, 251 FTEs have been diverted from other CDC efforts. Thus, the HIV epidemic has placed a severe strain on CDC personnel and functions. Additional personnel are urgently needed at CDC to expand both CDC's HIV programs and other CDC activities. In order to accommodate additional personnel, additional facilities will be necessary.

Obstacles to Progress

- Past FTE ceiling restrictions on hiring middle to upper grade levels of personnel have resulted in a decreasing number of these workers in the federal government. It has become common practice within the federal government that positions vacated by reassignment, promotion, or retirement are eliminated by attrition.
- The federal government's salaries and benefits packages often hamper the recruitment of quality personnel by CDC. Many qualified scientists and physicians who are interested in working for CDC will not do so because salaries are significantly lower in the public sector than in the private sector.
- The diversion of personnel from other programs within CDC to staff HIV programs has resulted in delays in other important public health programs. Specific health initiatives that have been delayed or not fully implemented because of personnel diversions include: expansion of efforts to control sexually transmitted diseases -- especially revising and updating training courses for STD control; development of programs to reduce and prevent injuries that result in chronic disabilities; building CDC's behavioral science capacity, an area essential to understanding which are the most effective prevention programs for injuries and disabilities and the best control programs for infectious and chronic diseases; implementing an intensive review of the prevalence of hepatitis A in the United States; and implementation of programs to prevent or reduce smoking during pregnancy.
- CDC is confined to a small and outmoded facility. The Office of Management and Budget (OMB) has thwarted recent attempts by CDC to expand and modernize this facility. Being housed in an antiquated facility has severely hampered CDC's ability to respond effectively to the HIV epidemic. In March 1988, OMB sent a memorandum to the President describing CDC's request for the construction of additional facilities as "wasteful." In contrast, in a November 1987 letter to Dr. James Mason, Director of CDC, from the General Services Administration (GSA), the GSA stated, "It is our commitment to support the Centers for Disease Control in your ef-

forts to upgrade and replace your aging physical plant at Chamblee, Georgia."

RECOMMENDATIONS

5-9 The Centers for Disease Control (CDC) must be adequately staffed at all times in order to successfully meet its public health mission, including HIV programming. The Commission's analysis of current and proposed HIV programs at CDC indicates that a total of 523 full-time equivalents will be required to be permanently assigned to HIV activities for FY 1989. CDC should be allowed to hire new staff in sufficient numbers to replace those personnel who have been diverted from other programs, *and* staff HIV-related programs with a full compliment of 523 full-time equivalents for FY 1989.

5-10 Congress, in conjunction with the Office of Personnel Management, should analyze the recruitment of personnel to the Centers for Disease Control (CDC). Federal salaries and benefits should be assessed. Following such an analysis, Congress should make every effort to enact legislation that will attract first-rate personnel to CDC.

5-11 The Office of Management and Budget (OMB) should follow both the General Services Administration and congressional mandates regarding the construction of facilities at the Centers for Disease Control. OMB should not undermine congressional intent.

Section VI. The Role of the State and Local Departments of Public Health

The state and local components of the public health system consist of state or territorial health departments, thousands of county and city health departments, as well as private, voluntary organizations such as community-based service organizations or community and migrant health centers. The structure and operating procedures for each of these organizations vary from locality to locality depending on a number of variables, including state or local law, the size of population served, and available financial resources. In some areas, city and county health departments operate only under state law, but receive local as well as state and federal funds. Other city and county health departments follow mandates established by their local governments that augment state law. In areas where local health departments are in place, the state health department often guides policy and functions in the important role of a coordinating body and the supplier of technical assistance. Many smaller cities and counties have no local health departments and receive public health services only from the state agency.

State and local public health agencies have several general responsibilities for any condition that affects the health of the general population. First, components of the local public health system collect and interpret surveillance data about a specific condition through the implementation of epidemiological studies and reporting of selected conditions by physicians, laboratories, and other elements of the health care system. Second, using the information gathered from such studies, local public health agencies then plan and implement programs to interrupt the spread of disease. Such programs may include public education campaigns, identification of infected people through the use of testing and partner notification mechanisms, or any other intervention designed to change behaviors in people who are at risk of becoming infected with the disease. Third, local public health agencies have the responsibility to provide selected treatment services for those members of society who cannot pay or who lack access to the health care system. Fourth, as a last resort, local public health agencies can use restrictive measures such as isolation to control the spread of disease. Fifth, local public health agencies evaluate the effectiveness of their efforts in controlling the spread of disease, identifying those strategies that have been successful and those that have failed. The sixth and final general responsibility of local public health agencies is to support appropriate community systems which contribute to the above. All of these are applicable to the HIV epidemic; however, there are obstacles to their full implementation.

Obstacles to Progress

- Funding for most HIV education and prevention programs occurs through grants. Due to the bureaucracy surrounding grant applications, valuable staff hours are continually used for filling out grant applications and not for direct delivery of prevention services.

- There is a lack of effective evaluation models and tools that can be applied to HIV prevention and

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education programs in order to measure their success. Evaluation of HIV prevention and education is difficult because it is a complex task to determine accurately whether behavior has changed as the result of any specific intervention. Long-term community-wide patterns of sexual and drug abuse behavior, and knowledge and attitudes pertaining to the HIV epidemic need to be measured in order to determine the effectiveness of a particular strategy. Lack of baseline infection prevalence data also hinders evaluation.

- Many personnel have been diverted from other programs to work in a crisis mobilization against the spread of HIV. The result of such diversion is that other programs such as the delivery of services for other sexually transmitted disease are being shortchanged, while there are still insufficient resources for HIV programs.

- The Commission is concerned that some individuals found to be HIV-infected through the military, Job Corps, State Department (including Peace Corps), and any other federal agency's screening processes are not being properly counseled and referred to the appropriate support agencies. This raises the possibility that the high-risk behavior of these individuals will not change and the opportunity to provide counseling will be lost.

RECOMMENDATIONS

5-12 The budgeting process needs to be streamlined to ensure that valuable staff time is used in the actual delivery of prevention programs. Funds should be made available to states for prevention services, such as counseling and testing, partner notification, education, and other services as a block grant administered by the Centers for Disease Control and delivered on a formula basis. That formula should be based on the following principles:

- Thirty-five percent of the funds should be distributed to the states providing:
  —a base amount to each state for the establishment of basic programmatic efforts as core support.
  —the balance of the amount to be distributed on a per capita basis and utilized by the state in accordance with a plan which incorporates the funding needs of local health departments, community health centers, community-based organizations, and other appropriate institutions.
- Fifty percent of the funds should be distributed among states on the basis of a formula reflecting the reported and the estimated HIV prevalence. Funding for FY 1991 should be awarded on the basis of reported prevalence only.
- Fifteen percent of the funds should be retained by the Centers for Disease Control for use in capacity building among states, technical assistance to states, federal demonstration and special projects, and research and training, including support for data collection.

5-13 Rational staffing strategies need to be developed at the state and local levels that identify HIV programs as separate entities or that fully incorporate them into existing structures. The end result, however, must be the full delivery of HIV prevention services and other important public health initiatives.

5-14 If not already in place, state and local departments of health should form an advisory committee that consists of health care professionals, community-based service organizations, community leaders, and others to advise on the most appropriate strategy to control the HIV epidemic, including methods to initiate and/or expand and maintain a counseling, testing, and partner notification program within the state. An official from the state department of health should be the designated chair of such a committee and should convene meetings at regular intervals.

5-15 State departments of health should coordinate the prevention and education activities of local health departments and community-based service organizations to ensure that there is neither the needless duplication of services nor an absence of needed services within a state. In so doing, state departments of health should assign one individual or office to meet regularly and work directly with local health departments, community-based service organizations, and professional medical and health care associations on HIV prevention and education activities.

5-16 Public health organizations should conduct studies that will enable public health professionals to determine the most valid ways to evaluate HIV prevention and education programs.

5-17 Experienced and well-credentialed specialists in human sexuality should be incorporated into the full-time staff and consulting staff of state and local public health departments and the Centers for Disease Control.

5-18 Department of Defense officials should meet with organizations representing state and local public health authorities to ensure that the policy for referral and follow-up for those found to be HIV-infected is implemented. Implementation should be made a part of the normal Military Entrance Processing Command's mission statement.

5-19 Officials from the Job Corps, the State Department (including the Peace Corps), and any other federal agencies conducting HIV screening should meet with organizations representing state and local public health authorities to ensure that a policy for referral and follow-up for those found to be HIV-infected is implemented. Implementation policies and procedures should be a part of agencies' mission statements.

5-20 All state and local health authorities should have systems for channeling HIV-infected applicants into appropriate counseling programs and partner notification and available medical services.

CHAPTER SIX: PREVENTION

Although the HIV epidemic has presented the public health system with a new set of challenges, the prevention of disease has been the primary mission of that system since its inception. Prevention refers to any action that interrupts or halts the progressive path of a disease. Effective preventive interventions which can be applied to the HIV epidemic include the implementation of widespread testing and counseling, partner notification, the pre-donation screening of potential blood and semen donors, the testing of donated blood and organs, restrictive measures, and the implementation of general and targeted education programs. Education is addressed in its own chapter. This chapter will address the other preventive measures mentioned above.

Section I. Testing and Counseling

The HIV antibody test is used for several reasons. First, it can determine an early clinical diagnosis of HIV infection which should immediately establish a strong link between an infected individual and a primary health care provider. Second, it is used to screen donated blood, organs, breast milk, and semen to protect the eventual recipient. Third, test results are used to establish incidence and prevalence data, critical to monitoring the epidemic. Fourth, test results can be used to initiate a process whereby partners are warned of their exposure to the virus. Finally, testing and counseling are a vital component in encouraging positive behavior change in an individual. The first four uses of the HIV antibody test are discussed elsewhere in the report. Here, we will focus on testing and counseling programs used as a vital component of an overall prevention strategy to promote behavior change in order to stem the spread of HIV infection.

Only a limited number of individuals potentially infected with HIV have been counseled and tested, and only a limited percentage (approximately five percent) of those infected with HIV have laboratory confirmation of their infection due to a lack of information, fears of testing, or limited access to voluntary testing and counseling services.

Testing provides an opportunity for effective education and counseling and, for some, the initiation of behavior modification. When a person has volunteered to be tested, or when his or her physician has determined with the individual's consent that an HIV antibody test is appropriate, the tested person's interest is elevated; in short, he or she is more likely at this point to pay attention than in merely receiving impersonal educational messages. The type and intensity of education and counseling linked to testing ought to be guided by two factors -- the test result and the reason the person offers for being tested. If the test result is negative, a simple brochure accompanying the result could, in some cases, suffice.

If a person expresses concern that his or her own behavior has led to the test or appears agitated at the time the blood is drawn, person-to-person counseling is appropriate both before and after the administration of the test. Particularly, counseling should be available for these persons between the time the test is administered and the result is known. The person who has participated in high-risk behavior but has a negative test result should receive counseling in an effort to ensure that he or she remains uninfected.

If the test result is confirmed positive, intensive counseling at the time the result is given is needed. Because of the significance of that result and the natural tendency for the infected person to block out much of the information given at the initial session while concentrating on the result itself, it is imperative that the initial counseling session include the presentation in writing of the implications of the test result and of the opportunity for further testing and for further counseling, which may be by referral. An effort should be made at the initial counseling session to link the infected individual with a primary care provider if that link does not already exist. Consideration should be given to providing take-home materials, such as brochures or audiotapes, so that the infected person can review the information at home if he or she so chooses.

Counseling of infected persons should also include the means to and the responsibility to avoid transmitting the virus to others, the responsibility and benefits of telling one's sexual or drug-using contacts about the test result, and the availability of public health services to inform those partners should the person be unable or unwilling to do so.

Many have suggested that testing should not be done in any circumstance without interpersonal counseling. This appears to be current public health policy, except in blood donating settings. While still using the testing process to promote education, however, it would be more prudent to differentiate the handling of those whose need for counseling is apparent from those for whom a simple brochure will suffice. Additionally, pre-test counseling can burden those who decide to seek an HIV test if done inappropriately. In some jurisdictions, pre-test counseling includes commentary which might discourage the person who has considered long and hard whether to seek the test. Pre-test counseling should support the decision for the test, should provide the person with basic information about the medical implications of the test, including the fact that diagnosis can lead to treatment and care, and should attempt to elicit the reasons the person is seeking to be tested without passing judgment on the decision.

Testing and pre- and post-test counseling for HIV should be available in a timely fashion for any individual who wishes these services. An adequate number of testing facilities must be made available for those individuals who have no personal physician or who will not seek testing services from their physicians so that any individual can determine whether he or she has been infected and can receive counseling, if needed, about healthy behavior.

Obstacles to Progress

- The perception that confidentiality may be breached is keeping people who believe that they may have been exposed to the virus from seeking testing and counseling services.

- The Commission heard from numerous witnesses who had been the target of discrimination as a result of a positive HIV antibody test. Some persons who fear such discrimination because of a positive test result or even admission that such a test is desired are choosing not to be tested.

- Access to voluntary testing is limited; long waiting periods in densely populated areas and lack of testing facilities in rural areas are impeding the ability of individuals to determine whether or not they are infected.

- State and local departments of health do not have adequate funding available to provide testing and counseling services on the scale that is needed for those who either cannot or will not get those services in the private sector.

- Many private physicians do not regularly offer HIV antibody tests to their patients, resulting in increased demands on public testing and counseling centers.

- Demand for service exceeds capacity at existing testing sites, both anonymous and confidential, in many areas. This results in unreasonably long waiting periods to receive both the administration of a test, as well as the communication of the result together with its appropriate counseling.

RECOMMENDATIONS

6–1 States should adopt statutes that ensure confidentiality in testing and in reporting to public health authorities.

6–2 People who fall into any of the following categories should seek testing and counseling services from their physician or public health agency, regardless of the presence or absence of symptoms:

- recipients of blood, blood products, donated semen, or organs since 1977.
- intravenous drug abusers.
- men who have engaged in sexual activities with other men.
- persons who have engaged in sexual activities with more than one partner since 1977.
- any person who believes his or her sexual partner, either current or past, is any of the above.

6–3 Voluntary testing for HIV infection on a nationwide basis should be widely encouraged by government at all levels, and physicians and other health care professionals should promote voluntary testing for their potentially exposed patients. To facilitate the performance of such tests, a variety of facilities such as mobile vans should be made widely available by funding through public health agencies and by the private sector.

6–4 Each state, through the local public health system, should increase the number and availability of anonymous and/or confidential testing and counseling sites.

6–5 State departments of health should make new funds available that will ensure that HIV testing and counseling services are a part of the services offered by sexually transmitted disease clinics, family planning centers, drug treatment clinics, and community health centers.

6–6 Private physicians should regularly offer their patients the opportunity for an HIV antibody test.

6–7 State and local departments of health should aggressively advocate the use of HIV testing and counseling services through public health education campaigns. These should highlight the assurance of confidentiality in order to induce more individuals to use the public health system. Special efforts should be focused on those geographic areas or members of groups in which there is evidence of high seroprevalence.

6–8 An incentive grant program should be created to support voluntary testing in counties or other well-defined geographic areas where the incidence of HIV infection rises above a designated level. These funds should be made available by the Centers for Disease Control on an expedited basis to applicants, who can be public or private non-profit agencies. Applicants must show that their program is consistent with the overall state HIV plan, and that those tested will be referred to appropriate community services. Funds may be used for both the testing itself and for aggressive outreach and advertising of the program in the target population.

6–9 Where anonymous testing services are offered, the appropriate state or local health authorities should assure that the services are consistent with those offered at other sites, including full access to partner notification assistance and reporting data generated into seroprevalence monitoring systems.

6–10 State laws should not prohibit private laboratories from performing HIV analysis.

Section II. Partner Notification

Both public health practice and case law makes clear that persons put at risk of exposure to an infectious disease should be alerted to their exposure. The Commission believes that there should be a process in place in every state by which the official state health agency is responsible for assuring that those persons put unsuspectingly at risk for HIV infection are notified of that exposure. Such a process will enable that agency to work with the infected individual and the patient's primary health care provider to assure that contacts are notified of their exposure and urged to take advantage of the opportunity for testing and counseling.

When interviewed appropriately, any person infected should be able to identify one or more persons from whom the infection may have come or to whom it may have been given. There are options for contacting those persons and ensuring that they, too, are aware of their risks. Those options include patient-managed referral and professional-assisted referral (with notification by an individual's health care provider or with notification by the health department).

Though the ideal would be to attempt to locate every sexual partner of every individual who tested HIV antibody positive, this is not realistic for most partner notification programs. Some states have already instituted partner notification, which is labor-intensive in nature. In light of limited public resources, they have established a priority list for partner notification. As an example, consider the woman who has been married for 30 years to a man who, unknown to her, is a bisexual, or the person who believes he or she is involved in a completely monogamous marriage when, in fact, his or her spouse has been having sex with others. These people are completely ignorant of their exposure to the virus and would probably remain so until either their spouse, their child, or they, themselves, developed the clinical symptoms of AIDS. The Commission firmly believes in these individuals' right to be notified of their possible exposure so that they can seek prompt medical attention and avoid potentially exposing others.

Those states which decide to fully fund partner notification as a major initiative to intervene in the HIV epidemic should consider also efforts to notify paraphernalia-sharing partners of intravenous drug abusers, preferably through training drug abuse treatment providers in partner notification procedures and then through increased funding for the purpose. Such an effort, however, should be considered only in addition to intensive efforts to notify sexual partners.

In keeping with the long tradition of the public health profession in respecting, in a confidential manner, both data and affected persons, the need to report identities should not be a bar to partner notification or to persons coming forward for testing. It is critical, however, that in proposing and implementing partner notification, the public health authorities involved must stress the confidential nature of the process and build confidence in those affected. Furthermore, there would be no purpose in public health authorities informing the notified partner of the identity of the person who disclosed the partner's name; this standard operating policy of traditional partner notification procedures should be followed also with respect to HIV.

Obstacles to Progress

- Difficulty exists in appropriately reconciling conflicts between rights of partners to notification and codes of medical ethics which have long and appropriately asserted that communications between doctors and patients are privileged and that doctors must maintain the privacy of patient communications.
- Many health care providers are neither skilled nor trained in providing the necessary counseling that is an integral part of partner notification.
- The application of traditional partner notification practices to this epidemic has been slow for a number of reasons, including: the lack of a cure which could be offered to the infected partner, unlike the case with other sexually transmitted diseases; the extreme fear of subsequent discriminatory retaliation; the limited resources available for HIV prevention services; and the perceived high cost per case for partner notification programs.

RECOMMENDATIONS

6–11 Any HIV-related confidentiality law should provide for confidentially reporting identity-linked test results to public health authorities.

6–12 Each state public health law should protect the confidentiality of an individual's reported infection status but allow for partner notification without informing the contacted partner of the identity of the infected person.

6–13 All state and local health agencies should initiate and be funded adequately to develop HIV partner notification programs without diverting resources from other sexually transmitted disease partner notification programs. These programs should include counseling, testing, and supportive follow-up for those individuals who are notified of their possible exposure.

6–14 To assure maximum use of resources, partner notification programs should be prioritized. Partner notification should begin with the partners of the following persons:

- hemophiliacs.
- persons who have received contaminated blood or blood products identified through "look-back" notification programs and other means.
- rejected military applicants.
- bisexual males.
- intravenous drug abusers.
- persons with multiple sex partners.
- persons with anonymous sex partners.
- infected prison inmates.

6–15 The public health department has an obligation to ensure that any partners are aware of their exposure to the virus. The public health authority and the primary provider should determine the priority of follow-up, the nature of verification that warning occurred, and the role of the identified individual in notification by considering such factors as:

- the patient's own statements, including commitment to provide notification directly.
- the patient's relationship with the party.
- the potential additional risk presented by a delayed notification.
- evidence that the third party is aware of the risk.

- the strength of the physician-patient relationship.
- other relevant factors.

6–16 Continuing education programs and the policies and programs of professional organizations should emphasize and reinforce the role of the public health authority and the ethical obligation of each health care provider to participate in the reporting process and partner notification programs, as well as include the scientific and behavioral information about the transmission of the virus.

Section III. Restrictive Measures

The primary focus in developing a comprehensive public health strategy to control HIV infection should be placed on those public health measures that are based on voluntary cooperation in risk-reducing behavior change: focused education; voluntary testing; counseling; partner notification; and treatment for drug abuse. However, these prevention measures even vigorously applied will be unsuccessful in persuading some small number of individuals to alter their behavior. When an individual poses a health risk to others by remaining noncompliant with recommended behavior change, appropriate control measures should be employed to achieve the public health objective of controlling the spread of HIV.

Compulsory control measures are usually authorized in state public health laws and could include limited isolation or supervised living arrangements. Such measures restricting the activities of individuals are appropriate to clearly culpable conduct that poses a significant risk of transmission when narrowly applied with adequate procedural safeguards. While a few states have amended their public health laws to permit some form of isolation with respect to HIV-infected individuals, the absence of a range of less restrictive compulsory measures and procedural deficiencies in many state public health statutes make it essential that states update these laws before employing them as a response to recalcitrant individuals.

Obstacles to Progress

- Traditional public health quarantine is not well suited to the limiting of HIV transmission.

- Many state public health statutes are deficient because of: basic structural problems caused by artificial boundaries erected between venereal and communicable diseases; the absence of clearly stated, objective criteria to guide public health officials in the exercise of their powers; the absence of procedures necessary for fair and impartial public health decision-making; and the absence of a range of less restrictive powers sufficiently flexible to allow supervision in the community.

- Public health officials and other interested groups fear that excessive attention to personal control measures may undermine public health goals by diverting attention and resources from effective prevention policies such as education, testing, counseling, and partner notification.

- Many people confuse public health restrictions designed to stop further spread with punitive measures intended to retaliate for past exposure of others.

RECOMMENDATIONS

6–17 States should immediately reform existing public health statutes designed to control the spread of communicable diseases according to the following guidelines:

- Rigid distinctions between venereal and communicable diseases should be removed.
- The public health statute should specify that use of personal control measures must be based upon a finding that the person is in an infectious state and is reasonably likely to transmit the infectious agent, posing a serious risk to the public health.
- The public health statute should allow for a range of control measures, imposing on the infected individuals requirements such as: to report all changes of address to the public health department; to attend sessions at appropriate places and times for the purposes of education, counseling, testing, medical examination or treatment; and if necessary, to be admitted to a hospital, detoxification center, or a clinic for treatment of drug dependency or sexually transmitted disease on an out-patient or day-patient or in-patient basis. Control measures should have the same procedural safeguards and enforcement should be for a specified period of duration.
- The statute must provide procedural safeguards of written notice, counsel, presentation of evidence and cross-examination, a clear and convincing standard of proof, and a verbatim transcript for appeal (the procedural safeguards required in civil commit-

ment of the mentally ill). An impartial decision-maker should hear the case prior to, or in cases of urgent necessity, immediately after the imposition of personal control measures. A process for review of the decision must be authorized. Due process must be accorded.

- State public health statutes should include strong uniform confidentiality protection.

6–18 Quarantine or isolation of HIV-infected individuals based only on HIV status without consideration of an individual's behavior is not appropriate and should not be adopted.

6–19 Less restrictive measures under public health laws should be exhausted before more restrictive measures, such as limited isolation, are taken.

6–20 In exercising powers of isolation under public health laws, there should be a heavy burden on the public health official to determine that these are necessary and appropriate and that a factual basis exists for making a determination to isolate.

Section IV. Safety of the Blood Supply and Donated Tissue

As of June 6, 1988, 2,399 of the people diagnosed with AIDS had acquired the infection through transfusions of blood, blood products, or the clotting factors used to treat hemophilia. The initial response of the nation's blood banking industry to the possibility of contamination of the nation's blood by a new infectious agent was unnecessarily slow. However, important lessons were learned from this chapter of our blood banking history which cannot be dismissed as we face future problems. The Commission believes strongly that the blood banks should not delay any longer the screening for another blood-borne virus, HTLV-1, which is believed to be the cause of adult T-cell leukemia/lymphoma and a severe neurological disease known as tropical spastic paraparesis (TSP).

Technological advances in blood screening tests and the purification process of the clotting factor have rendered the nation's blood supply as safe as it ever has been; however, this does not imply that it is completely free of risk. Transfusions of blood can be lifesaving, but it must be remembered that their side effects can cause serious illness or death.

The most significant complications of blood transfusions are immunologic reactions and the transmission of infectious disease agents, including the transmission of HIV. While donor screening procedures combined with pre-transfusion laboratory tests can reduce the incidence of the transmission of diseases such as hepatitis, syphilis, malaria, and HIV, they cannot eliminate the risk.

It is for these reasons that the Commission supports aggressive screening of the nation's blood donors along with thorough testing of the blood that is donated. However, the surest preventive measure with regard to the blood supply is to eliminate the exposure of a patient to the blood of others, whenever possible.

The same principles apply to donated organs and semen. An organ or semen that has been infected with HIV can transmit that infection to the recipient. The same type of infection control that is practiced with the blood supply needs to be applied equally to organ transplants and artificial insemination.

Obstacles to Progress

- Many physicians and hospitals do not have an adequate understanding of and, therefore, have not adequately informed their patient population about the availability of alternatives to traditional transfusion therapy.

- Because a majority of the fresh blood supply is derived from voluntary donations, the blood banking industry must actively recruit numerous donors into the system. As many donors as possible are accepted.

- The Food and Drug Administration (FDA) has the responsibility to set the standards for the blood industry; however, it relies heavily on that industry for advice on what standards to set -- a relationship that presents a significant opportunity for conflicts of interest to arise.

- Health care financing plans that are applied to traditional homologous transfusion therapy often cannot be applied to autologous transfusion therapy.

- Some regional blood centers have been hesitant to promote strategies that minimize the use of transfusion therapies, since their operating income is derived from the sale of blood and blood products.

- Not all facilities have instituted notification procedures for those persons transfused with blood or its components since 1977. Not only persons transfused but also their sexual partners may have been exposed to infection.

- Blood banks are currently using a self-deferral system whereby those individuals who have practiced behaviors that put them at greater risk of becoming infected with HIV are encouraged not to donate blood. Because this is an entirely voluntary process, some individuals who are at greater risk of HIV infection continue to donate blood despite attempts to exclude these individuals from the donor pool.

- Because of the significantly increased workload that the HIV epidemic has presented and the lack of human and financial resources, manufacturers of blood screening tests have an extremely limited access to FDA review staff. This slows the introduction of useful new screening products to the market.

- Recent advances in technology have made clotting factors safer. However, the application of such technology has resulted in a four- to eightfold increase in cost to the patient. This substantial rise in cost has resulted in considerable concern that third-party payments could be jeopardized and access to such products denied.

RECOMMENDATIONS

6–21 As soon as is practically possible, but no later than July 1, 1989, agencies which license and certify health care facilities should make a condition for licensure, a program to notify all recipients of blood or blood products since 1977 of their possible exposure to HIV. Such "lookback" notification should include a statement about the benefits of receiving counseling and testing services and provide information about where such services are delivered. This may be done in conjunction with local or regional blood banks or the state or local health department. Notification of partners of these persons is the responsibility of public health agencies. If licensing agencies do not take such immediate steps, Congress should then enact a law that requires it.

6–22 Informed consent for transfusion of blood or its components should include an explanation of the risks involved with the transfusion of blood and its components, including the possibility of HIV infection, and information about appropriate alternatives to homologous blood transfusion therapy. These specifically include pre-deposit autologous blood, intra-operative autologous transfusion, hemodilution techniques, and post-operative collection.

6–23 The Food and Drug Administration, in an effort to ensure that the nation's blood supply is never contaminated, should define a mechanism that quickly identifies a new threat to the safety of the blood supply and implements procedures that will abrogate that threat.

6–24 The Food and Drug Administration, in collaboration with the Blood Products Advisory Committee, should identify principles on which to base the introduction of new testing requirements and actively assess additional direct or surrogate tests in order to consider their introduction. Surrogate tests, such as serology for syphilis, should be required.

6–25 The Food and Drug Administration (FDA) should restructure the membership of its Blood Products Advisory Committee so that it reflects the entire blood products community, the plasma industry, and members of the related academic community, as well as one or more public members. In its capacity as an advisory body to FDA, this Committee should actively monitor advances in research and development and recommend changes in policy and practice that should be implemented by the blood industry which will promote the further safety of the blood supply.

6–26 In health care facilities, all reasonable strategies to avoid homologous transfusion (blood from others) should be implemented including pre-deposit autologous transfusions, hemodilution techniques, intra-operative autologous transfusions, and post-operative collection. Health care facilities should offer aggressive in-service training to their staff, particularly blood banking and transfusion services personnel, to bring them up-to-date on current autologous transfusion therapy techniques.

6–27 The Health Care Financing Administration and the Health Resources Services Administration working with the National Hemophilia Foundation should develop alternative payment mechanisms to make clotting factor treatment affordable for patients.

6–28 The Centers for Disease Control should make grants available to Comprehensive Hemophilia Treatment Centers to be used for the design and implementation of risk-reduction and psychosocial support programs. The objectives of such programs should be to educate HIV-infected hemophiliacs about techniques to avoid the further transmission of the virus either sexually, perinatally, or through the sharing of needles.

6-29 All blood banking facilities should implement screening procedures to identify the presence of HTLV-1 in the homologous blood supply.

6-30 The Food and Drug Administration (FDA) should fund an independent scientific organization to initiate a six-month study of the extent, purpose, and effectiveness of existing blood donor registries and the effect that expansion and/or requirement of donor registries would have on the safety of the blood supply. The independent organization should report the results of such a study to both FDA and the Congress.

6-31 Health care financing plans should treat autologous transfusion therapy no differently than homologous transfusion therapy. Coverage should apply to both.

6-32 All states should immediately enact legislation requiring the registration of facilities for the collection, storage, and transfusion or administration of blood, organs, other tissues, semen, and breast milk, in order to facilitate enforcement of regulations requiring screening for HIV.

Section V. Laboratory Quality

The HIV antibody tests now available are reliable when performed under well-supervised conditions in excellent laboratories. The consequences of poor quality control in the laboratories that perform diagnostic tests can have devastating effects on people's lives. This problem is brought into especially sharp focus by the consequences of a misdiagnosis of HIV infection due to disorganized laboratories. This applies to all laboratory tests, not just those for HIV.

Continued public awareness of this situation discourages individuals from seeking HIV testing and community groups from recommending testing. Currently, there are 98,000 unregulated physician laboratories in the United States. Only 16 states regulate these physician laboratories. There are 37 states that regulate independent laboratories and 40 states that regulate the labs in hospitals. There is no standard regulation policy among even these. FDA regulates laboratories that engage in interstate commerce and the Health Care Financing Administration regulates laboratories that bill Medicare or Medicaid for services.

The initial screening test for HIV, known as the Enzyme-Linked Immunosorbent Assay (ELISA), is a relatively simple test to perform and interpret. Because the ELISA is more sensitive than it is specific, however, any positive results from an ELISA screen need to be confirmed by a more specific test before they can be trusted. The most commonly used confirmatory test is a Western Blot Assay (WBA), a more complex -- and expensive -- test whose performance is currently limited to a relatively few laboratories.

It is critical that laboratories performing WBAs and/or other sophisticated confirmatory tests employ highly skilled technicians and stringent quality standards, since it is the confirmatory test result that is definitive to diagnosis. The HIV antibody tests are extremely accurate, and false positives are no longer a problem when repeatedly positive ELISA screening tests are followed with the confirmatory Western blot tests done in qualified laboratories. Therefore, we suggest that FDA and CDC in cooperation with other government agencies consider capabilities for the confirmatory HIV antibody testing.

This could be done by sending "known" tests to certified confirmatory HIV antibody testing laboratories at intervals to check their personnel for accuracy. Any laboratories having unacceptable clerical mistakes or other personnel errors could face a problem in maintaining their continued certification.

Obstacles to Progress

- Many labs in the United States have no outside review of quality.
- The Health Care Financing Administration has reduced the number of its laboratory inspectors by 30 percent.

RECOMMENDATIONS

6-33 The Health Care Financing Administration, the Centers for Disease Control, the Food and Drug Administration, the National Governors Association, and the Association of State and Territorial Health Officials should develop a model state laboratory licensing law that addresses: types and levels of tests performed; personnel standards; use of proficiency tests; on-site inspections; and participation in education programs.

6-34 The Public Health Service should provide funds that will enable states to implement the above model law.

6-35 The Food and Drug Administration should impose criteria at least as stringent as the model state law on laboratories involved in interstate commerce.

6-36 The FY 1989 allocation for the Health Care Financing Administration should be increased so that it can expand its laboratory inspection efforts.

6-37 Medical professionals and laboratories should immediately adopt the policy of not reporting positive initial screening test results (such as ELISA) to the tested individual or to public health authorities without first having confirmed such positive results by a Western Blot Assay or other approved test.

6-38 Performance of the Western Blot Assay or other confirmatory tests should be restricted immediately to laboratories which currently meet high quality standards, and priority should be given to assessing labs currently doing such tests for possible certification to continue their practice.

6-39 Consideration should be given to contracting out laboratory assessment activities to professional organizations experienced in evaluating laboratory quality.

Section VI. Therapists' Role in Prevention

Professional therapists and counselors (such as marriage, family, and sex therapists, psychiatrists, psychologists, pastoral counselors, social workers) are an underutilized resource in the HIV epidemic. They play four major roles in prevention:

- counseling those who are infected on how to avoid spreading the disease to others;
- counseling their general patient population, most of whom are not infected, on how to avoid becoming infected;
- encouraging self responsibility and social responsibility; and
- test-linked counseling.

Obstacles to Progress

- The therapists' role in prevention has been generally overlooked.
- Many professional associations have not recognized or encouraged their memberships to serve this function.
- Qualified counselors to perform post-test counseling are in short supply.
- Funding for post-test counseling is not adequate.

RECOMMENDATIONS

6-40 Therapists and counselors should counsel their patients/clients who are participating in behaviors that make them vulnerable to infection with HIV with the purpose of behavior modification.

6-41 Therapists and counselors treating HIV-infected patients/clients should encourage sexual and social responsibility.

6-42 Therapists and counselors should be encouraged to become well-informed and up-to-date on HIV infection. Professional associations should be encouraged to provide this education.

6-43 Incentive programs and grants should be developed to create and attract more qualified counselors to perform test-linked counseling.

6-44 Therapy and counseling associations should cooperate in establishing an interdisciplinary advisory committee to develop guidelines for therapists on advising their patients about protecting themselves, their partners, and their unborn children from infection.

CHAPTER SEVEN: EDUCATION

It is critical that the term "education," when used in conjunction with the HIV epidemic, is not associated only with a formal setting such as the classroom. HIV-related education needs to take place in all locations, both within and outside of society's mainstream. Education about HIV needs to occur both inside and outside of our nation's schools and workplaces. No corner of society can be neglected as educational programs about the HIV epidemic are developed and implemented. The Commission recognizes the vital role that health care workers occupy in meeting the educational needs of our society as a whole. Their own, unique educational needs are addressed in the chapter on patient care. The responsibility of employers to provide the nation's work force with general health information, including information about HIV, is addressed with other workplace issues in the chapter on societal concerns. This chapter will address those educational strategies that can be implemented for the rest of society.

During the last year, there has been a great deal of sometimes acrimonious debate over the content of HIV education. The Commission is concerned that, in the promotion of the personal moral and political values of those from both ends of the political spectrum, the consistent distribution of clear, factual information about HIV transmission has suffered. HIV education programs for example, should discourage promiscuous sexual activity and recognize the benefits of abstinence and monogamy; however, they need to be explicit in nature so that there is no confusion about how to avoid acquiring or transmitting the virus. The Commission firmly believes that it is possible to develop educational materials and programs that clearly convey an explicit message without promoting high-risk behaviors. All HIV education programs should emphasize personal responsibility for one's actions. Actions have consequences.

No citizen of our nation is exempt from the need to be educated about the HIV epidemic. The real challenge lies in matching the appropriate educational approach with the people to be educated. It is not the role of the federal government to dictate to local communities their values, and too much time has been wasted on this debate when educational materials are needed which clearly present the facts about AIDS and HIV transmission. In a similar vein, those who seek to use HIV education programs to further their own ideology of whichever stripe cannot expect federal funds for this purpose. In short, the federal, state, and local governments should convey the current medical and scientific facts to the American public and they, in turn, will build curricula suited to their own community value systems. When these curricula are constructed well, with all responsible local entities working in a collaborative way to help ensure their efficacy, the educational response of one region of the country can be expected to differ from that of another. Both responses should be applauded.

The Commission believes that several education initiatives are of such vital importance to the effective preventive management of the HIV epidemic that they must be implemented immediately. These include: general public education, distinct population targeting, and school-based education.

Obstacle to Progress

- The educational response to the epidemic in many areas can best be described as haphazard. There is often a lack of statewide planning that

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involves input from local health departments, community-based AIDS service organizations, schools, philanthropic organizations, religious institutions, and other appropriate voluntary initiatives.

RECOMMENDATIONS

7-1 All HIV programs should emphasize personal responsibility for one's actions. Actions have consequences.

7-2 State departments of health should assume the lead responsibility for coordinating HIV-related educational initiatives within each state. State departments of health should develop a one-year plan and a five-year plan that clearly define the state's educational response to the HIV epidemic. Such a plan must include the input and identify the roles and responsibilities of local health departments, professional health care associations, community-based AIDS service organizations, state and local education agencies, philanthropic organizations, religious institutions, and other appropriate voluntary initiatives. The one-year plan should be developed by September 1, 1988 and the five-year plan by January 1, 1989.

Section I. General Public Education

In a national response to an epidemic, there is some information which every citizen should receive regardless of race, sex, age, geographic location, literacy level, or degree of risk for infection. This information sets the tone for more specific education and prevention programs and helps sustain our community effort as a whole. General information about the HIV epidemic should include basic facts about HIV infection and AIDS, the ethical obligation to be both non-discriminatory and caring, and resources where a person can obtain more detailed information.

The Role of the Media

The media, both electronic and print, have a tremendous opportunity to enhance the public's knowledge and attitudes about the HIV epidemic through the information that it chooses to present. There have been many examples of responsible -- and unfortunately some examples of irresponsible -- reporting and programming on the HIV epidemic. The Commission realizes that media activity alone cannot bring about positive behavior change; however, it can support the education activities of a community by providing constant, accurate information about the epidemic.

Obstacles to Progress

- Inaccurate or incomplete information about the HIV epidemic is, at times, presented by the media, both in their entertainment and news activities.
- Public service announcements are often broadcast at times when a majority of the population are not watching television or listening to the radio.
- Media events, such as a special program about the HIV epidemic, public service announcements, or a news story, often are not coordinated with state or local health departments or community-based organizations, resulting in an unexpected high demand for services or information which cannot be met because of lack of notice.
- The entertainment industry often portrays promiscuous sexual activity and drug use in a glamorous light and fails to mention the frequent negative consequences of such activity.
- Geographically specific HIV infection data and other related information are not available to the media in all parts of the country.

RECOMMENDATIONS

7-3 The electronic media should schedule a majority of its HIV-related public service announcements at times when they will receive high visibility.

7-4 The Centers for Disease Control should create a weekly newsletter targeted specifically to the media that provides accurate, current information about the HIV epidemic, including data as geographically specific as possible. Such a newsletter should include a telephone number that can be called during regular business hours to receive the most up-to-date information about the HIV epidemic. Such a newsletter should be widely advertised through trade journals, conferences, and other appropriate avenues, and should be offered on a subscription basis at reasonable cost.

7-5 State and local health departments and community-based AIDS service organizations should sponsor seminars for members of the local news and entertainment media. The seminars should help coordinate activities, provide current and accurate information about the HIV epidemic, and explain HIV-related services that are being offered throughout a community or state.

7-6 The entertainment industry should portray irresponsible sexual and drug-related activity in a manner that reflects the potentially detrimental emotional and physical consequences of such behavior and should shift focus to presenting the appeal of healthy behavior.

7-7 The Centers for Disease Control (CDC) should conduct a 90-day study on the effectiveness of purchasing paid advertising, in addition to requesting advertising at no cost, to present information about the HIV epidemic to the general public. If the study concludes that such a purchase would be effective, CDC should purchase paid advertising.

The National AIDS Hotline

The National AIDS Hotline operated by the Centers for Disease Control (CDC) serves an important function in providing the general public with a toll-free telephone number that can be called 24 hours a day. The Hotline counselors can provide the caller with general information about the HIV epidemic, answer specific questions, provide information about HIV-related services that are available within a specific community, and take requests for publications offered by the National AIDS Clearinghouse. The Hotline offers one of the greatest opportunities to provide educational information in a professional, confidential, direct manner to any member of the public.

Obstacle to Progress

- Many citizens, including those most at risk of HIV infection, are not aware of the National AIDS Hotline and the services it offers.

RECOMMENDATIONS

7-8 The Centers for Disease Control (CDC) should aggressively market the National AIDS Hotline through its ongoing HIV education and information campaign. The toll-free number, along with a description of services offered, should be widely publicized in informational pamphlets and public service announcements that are sponsored by CDC.

7-9 The National AIDS Hotline should continue to offer 24-hour counseling to respond to the needs of any caller. The Centers for Disease Control should ensure that there are sufficient operators on duty at all times to meet demand.

7-10 The Centers for Disease Control should equip the National AIDS Hotline with communications capability for the hearing impaired by August 1, 1988.

7-11 The National AIDS Hotline should serve as a referral center for the following services: community-based service organizations, advocacy and protection programs and services, availability of drug and vaccine trials, counseling and testing centers, and federal, state, and local agencies that deliver HIV-related services.

The National AIDS Clearinghouse

The National AIDS Clearinghouse operated by CDC is intended to tell the public where pertinent information about the HIV epidemic can be obtained. It has also been described as a resource for public health officials and health care providers.

Obstacles to Progress

- The only general information publications that the National AIDS Clearinghouse currently offers are those documents produced, either directly or under contract, by the federal government.
- The National AIDS Clearinghouse has not been connected with the existing electronic network that serves state and local public health departments.

RECOMMENDATIONS

7-12 The National AIDS Clearinghouse should continue to make available free of charge those documents pertaining to the HIV epidemic produced by the federal government.

7-13 The Centers for Disease Control (CDC) should conduct a potential user survey of state and local departments of health, community-based service organizations, and individual practitioners to determine their information requirements. At the conclusion of the survey, CDC should then ensure that the clearinghouse has the necessary funding and direction to meet those requirements.

7-14 The National AIDS Clearinghouse should collect and disseminate educational materials, including curricula and methods of instruction related to both the medical and the societal aspects of the HIV epidemic that are produced by federal, state, or local agencies or community-based service organizations. The Clearinghouse should make a catalog of these materials available free of charge, and provide copies of such material on a fee-for-service basis.

7-15 The National AIDS Clearinghouse should collect and actively disseminate to education associations, chief state school officers, school districts, and others school-based educational materials, including sample curricula and methods of instruction concerning the HIV epidemic. The Clearinghouse should make a catalog of these materials available free of charge, and provide hard copy of such material on a fee-for-service basis.

7-16 The National AIDS Clearinghouse should make federally produced documents available in braille and on audio cassette.

7-17 The National AIDS Clearinghouse should become connected with the electronic information networks that serve state and local departments of health.

Section II. Distinct Population Targeting

While the HIV epidemic affects all segments of society, it is important to recognize that each distinct segment has its own unique educational needs. The Commission recognizes that it is behavior, not membership in any particular group or population, that places a person at greater risk for HIV infection. However, the educational response to the epidemic needs to acknowledge the eclectic nature of our society and effectively match the proper educational approach with a receptive target population.

The Commission has heard testimony from members of many different distinct populations, including homosexual men, blacks, Hispanics, students, advocates for runaway and homeless youths, the hearing-impaired, and advocates for the developmentally disabled. But for all these groups, or for any other distinct population, the principles involved in the development of curricula and methods of presentation are the same. The design and implementation of educational programs must have significant input from members of the targeted population so that each program will be relevant, appropriate in language, and effectively reach the intended audience.

State and local public health departments, in conjunction with community-based AIDS service organizations and other community leaders, are in the best position to understand the cultural, language, lifestyle, educational, and behavioral components of their communities. It is because of this understanding that the assessment of the education needs of a community must occur at the local level, reflecting local community values.

Following that assessment, local communities must develop and implement comprehensive HIV education strategies that will meet the community's specialized needs. However, local communities will not be able to meet their prevention and education needs without significant financial and technical support from both the state and federal governments and the private sector.

Obstacles to Progress

- Comprehensive, integrated strategies developed by state and local departments of health in conjunction with community-based organizations often do not exist, resulting in the duplication of some services and the absence of others.
- Community-based organizations often lack expertise in program development, management, and grant writing.
- National information and education campaigns implemented to date have not been significantly targeted to -- and therefore do not reach -- distinct populations, such as minority communities.
- The basic health care needs, including education and prevention programs, of minority populations have not been met in the past, a situation that is being compounded by the HIV epidemic.
- Federal, state and local funding of community-based initiatives has been scarce and uncoordinated. As a result, communities have been unable to develop and implement adequate long-term prevention and education services.
- Funding patterns have not enabled community-based education initiatives to be adequately evaluated by their sponsors, making it difficult to design further programs with any certainty that they will be effective.

RECOMMENDATIONS

7-18 The Centers for Disease Control (CDC), in conjunction with the Public Health Service Office of Minority Health, should increase its information and education programs targeted toward minority communities. In so doing, CDC should contract directly with minority advertising agencies and community-based service organizations to develop a media-based information and education campaign including the input from the community-based service organizations targeted toward specific minority populations in

10 metropolitan areas that have significant minority populations. CDC and the Office of Minority Health should choose those 10 cities. The content of such a campaign should be clear and unequivocable and culturally relevant to the communities. CDC should be responsible for the content of such a campaign and the advertising agencies should be responsible for determining the most effective way to package and deliver that information. The major objective of such a media campaign should be to inform people about activities that place them at risk of becoming infected with the virus and to identify HIV-related services that are available within a specific community. The result of this media-based minority information and education initiative should be the creation of model media-based public information programs that can be easily replicated in other parts of the country. Consideration should be given to use of extended presentations, not just spot announcements.

7-19 Once such a media-based campaign has been developed, the Centers for Disease Control should make funds available to state and local departments of health so that targeted paid advertising can be purchased in media outlets specific to minorities and other distinct populations. Such funding should reflect the need to present paid programs, not just spot announcements.

7-20 When federal money is used to finance all or a part of an educational program, the Centers for Disease Control should ensure that all program sponsors have a detailed evaluation component included in the program that measures, among other indicators, changes in behavior, knowledge, and attitudes pertaining to the HIV epidemic.

7-21 State and local departments of health should recognize the disproportionate way in which the HIV epidemic has affected minority populations. They should, at a minimum, allocate a percentage of their HIV prevention and education budgets directly proportional to the minority populations within their jurisdiction for the delivery of prevention and education programs to those minority populations. State and local departments of health should ensure that all educational programming produced is linguistically relevant to the targeted audience.

7-22 State and local departments of health should ensure that easily accessible HIV-related services, including public health education programs, peer counseling, and other risk reduction interventions, are being offered within their jurisdictions.

7-23 The Centers for Disease Control, states, and localities should increase funds to state and local health departments to initiate and/or increase HIV prevention and education activities. These activities should include public health education campaigns, peer counseling, outreach education, and other risk reduction interventions.

7-24 The Centers for Disease Control (CDC) in conjunction with states should increase funds and technical assistance in program development, management, and fundraising (including grant writing) to community-based service organizations so they can develop appropriate prevention programs. These programs should include public health education campaigns, peer counseling, outreach education, and other risk-reduction interventions. Where federal money is involved, CDC should require that all grant applicants include detailed evidence of their ongoing coordination with state and local departments of health.

7-25 Because community-based organizations have successfully used their credibility with hard-to-reach populations to bring their educational messages to a broad audience, state and local health departments should provide support to responsible community-based organizations providing such services.

7-26 All citizens and philanthropic groups should be challenged to target at least a portion of their activities over the next 10 years to programs and services which will further reduce the risk of HIV transmission. Economic and political realities make it impossible for public funds to support all possible activities related to control of HIV infection. Public funds will only sustain basic services and may not be able to provide the specificity needed by some groups. Private support can extend the services and can experiment creatively with new approaches.

7-27 The Department of Health and Human Services (HHS), the Department of Housing and Urban Development (HUD), and states should increase funds to national and local organizations that provide services to homeless and runaway youth. The funds should be used to initiate and/or expand programs designed to provide appropriate education strategies for runaway and homeless youth. When federal money is involved, HHS and HUD should require that all recipients provide detailed evidence of ongoing coordination with state and local departments of health and other social service agencies. Funding should be based on an established history of positive interventions with homeless and runaway youth and innovative program design.

7-28 The Centers for Disease Control should make funds available to organizations representing persons with disabilities and special education professionals to develop materials and disseminate information about HIV infection. Such materials should be targeted to the unique needs of individuals with mental retardation, mental illness, hearing impairments, visual impairments and other learning and physical impairments.

7-29 The Centers for Disease Control should make evaluation grants to state departments of health to conduct special studies to determine what programmatic interventions are most effective in reducing transmission of the virus in various communities. Detailed information about those programs, including program content and implementation strategies, should be provided to other state and local departments of health, as well as national and community-based AIDS service organizations, so that those programs can be replicated in other parts of the nation.

Section III. School-Based Education

The Near-Term Response: Immediate HIV Education

A two-part response to the epidemic is required from the nation's elementary and secondary school system. The first part must happen in the short term. It is the opinion of the Commission that the provision of HIV education in our schools is of vital importance and must be introduced across the nation immediately. Some states have already ensured that this is happening; the rest must follow their lead. The decisions about appropriate content and methods of instruction should be determined at the local level; however, both elementary and secondary school students should receive such education. Students must be provided with current and accurate information about the HIV epidemic that is appropriate for age so that they can make informed decisions about their behavior and avoid those actions that put them at risk for HIV infection. School-based education should highlight the benefits of character development, abstinence, and monogamy. By ensuring that appropriate education about the virus is provided in the elementary and secondary school system, we can help our younger generation avoid the tragedy we are witnessing today.

The second part is the long-term response, which will have a far greater pay-off when fully implemented; that is the introduction of a comprehensive health education curriculum for all grades K through 12. This broader topic is discussed later in this chapter.

Obstacles to Progress

- The HIV epidemic involves some of our most personal behaviors, and many find it difficult to incorporate information about the epidemic and those behaviors into a classroom program.
- Many communities still do not believe that the HIV epidemic is something that will ever affect them and, therefore, see no need to provide HIV-related education to their children.
- Funding that will allow HIV education programs to be delivered is not in place.

RECOMMENDATIONS

7-30 State boards of education should mandate that an HIV education curriculum with appropriate content for age be offered to all students at each schooling level (e.g., elementary, middle, and high school) throughout the state.

7-31 If such a system is not already in place, the state director of health and the chief state school officer in every state should establish a formal mechanism to exchange information about the HIV epidemic, including current technical information and model education programs.

7-32 School staff who deliver HIV education should receive extensive in-service education before they begin instruction. The content of the in-service education should be designed in conjunction with state education and health agencies. No member of the school staff should be forced to deliver education about HIV if he or she is not comfortable with the subject.

7-33 Local school boards should establish an advisory committee, consisting of school board members, professionals from the state and/or local public health department, parents, teachers and students, to develop an HIV education curriculum. The committee should meet at frequent intervals until the curriculum is enacted and thereafter at least annually to monitor and evaluate HIV school-based education.

7-34 The Department of Education, the Centers for Disease Control, states and localities should increase funds to national education organizations, school districts, and other educational entities to design and implement HIV education curricula.

7-35 The Centers for Disease Control should increase funds to colleges and universities for creation and/or expansion of HIV prevention and education programs on campus. The schools should use these funds to educate their students about the medical aspects, including appropriate risk-reduction techniques, and the societal aspects of the epidemic.

7-36 State and local health departments should conduct conferences to provide current technical information about the HIV epidemic to state and local school boards, principals, and teachers. Such conferences should be held regularly, based on the amount of new information available or requests for updated information.

7-37 State and local health departments, in conjunction with state and local school boards, should conduct conferences to provide current and accurate information about the HIV epidemic and school-based education initiatives, including the description of model programs, for parents of school-age children. Such conferences should be made available free of charge to all parents of school-age children, and should be held regularly, based on the amount of new information available, turnover in the student population, or requests for updated information.

The Long-Term Response: Comprehensive Health Education

The Commission strongly believes that the introduction of an age-appropriate comprehensive health education curriculum that encompasses grades K through 12 is long overdue. Providing our nation's school children with education about HIV transmission, as recommended in the near-term response section, is a significant step. However, it represents only a stop-gap measure to correct a larger problem. The expert witnesses who testified before the Commission clearly demonstrated that the problems that are afflicting youth today -- such as sexually transmitted diseases including HIV infection, drug abuse, school-aged pregnancy, and decisions to drop-out or run away -- are all inseparably intertwined. The HIV epidemic provides a unique impetus to address these problems in total rather than continue the piecemeal, fractured, and largely ineffective approach that is being undertaken today.

The heaviest burden of illness in the technically advanced countries today is related to individual behavior, especially the long-term patterns of behavior often referred to as "lifestyle." In the United States, it is reliably estimated that 50 percent of mortality from the 10 leading causes of death can be traced to lifestyle -- health-damaging behaviors such as smoking, drinking, eating too many calories and too much fat, and inactivity. Other behaviors highly relevant to health and disease -- both mental and physical -- are responses to the stresses of events in life.

What we do early in life lays the foundation for all the rest. The early years can provide the basis for a long, healthy life span. Early preventive intervention tends to be exceptionally cost-effective. Health and education are closely linked in the development of vigorous, skillful, adaptable young people. Investments in health and education can be guided by research in biomedical and behavioral sciences in ways likely to prevent much of the damage now being done to children and adolescents.

The onset of adolescence is a critical period of biological and psychological change for the individual. Puberty is one of the most far-reaching biological upheavals in the life-span. For many, it involves drastic changes in the social environment as well: the transition from elementary to secondary school. These years (ages 10 to 15) are highly formative for health-relevant behavior patterns such as the smoking of cigarettes or avoidance, the use of alcohol or other drugs or abstaining, the driving of automobiles and motorcycles, habits of food intake and exercise, and patterns of human relationships, including pre-marital sexual activity leading to high-risk pregnancy and sexually transmitted disease or abstinence. Before health-damaging patterns are firmly established, there is a crucial opportunity for preventive intervention and affirmation of healthful living and self-respect.

Despite the drastic biological, social, and technological changes surrounding adolescence that have taken place during this century, there appear to be fundamental human needs that are enduring and crucial to survival and healthy development:

- The need to find a place in a group that provides a sense of belonging.
- The need to identify tasks that are generally recognized in the group as having adaptive value and that thereby earn respect when skill is acquired for coping with the task.
- The need to feel a sense of worth as a person.
- The need for reliable and predictable relationships with other people, especially a few relatively close relationships.

The experience of industrialized nations suggests that rapid social changes, the breakdown of family supports, and prolongation of adolescence are associated with an increase in behavior-related problems such as substance abuse, school-age pregnancy, and education failure. The opportunities for prevention rest heavily on finding constructive ways to meet the basic aspirations of adolescent development in a new social context.

The Commission believes that comprehensive health education, taught through a life sciences curriculum, offer a distinct opportunity to stimulate early interest in science and to learn how to deal more effectively with matters of deep human concern. The life sciences, by stimulating children's interest in understanding nature, can also lead the way to a deeper study of other scientific disciplines such as chemistry and physics.

In this context, then, health education includes at least three components in a system: (1) education in terms of classroom instruction and curriculum; (2) school policies that support the knowledge and skills that are developed through such education; and (3) governmental policies and regulations that reinforce both of the above. But it is the school health program that is "comprehensive" in taking into account different levels of a total system from the individual, organization, community and government, and *not* the curriculum that is so often referred to as "comprehensive". A truly "comprehensive" health education program is one that integrates basic concepts in biological and behavioral sciences, and opportunities to apply problem-solving and decision-making skills in the context of real-life individual and social issues.

An important goal in understanding human biology will be to permit better solutions -- with less strife and more informed public participation -- to biological aspects of social problems, such as environmental hazards. Knowledge of human biology is particularly important for decisions that relate to health -- decisions on whether to use alcohol, cigarettes, or drugs; to understand what constitutes healthy diet and exercise; decisions about sexuality -- as well as decisions on when and how to seek health care. Thus, education for health is a potentially powerful offshoot of education in the life sciences.

The objectives of teaching life sciences to all students is to provide a major stimulus to the biology curriculum for young adolescents. An age-appropriate comprehensive health education program (K through 12) would teach students essential concepts in biology and then relate these concepts to problems that students encounter in their daily lives. These programs should emphasize personal responsibility for one's actions. Actions have consequences. It would promote healthy behaviors, through the knowledge they will gain about themselves -- and what they can do to their own bodies and their own lives.

The Commission believes it is time to allow our children to become part of the solution to all health threats they face, and to do this by engendering in them a fundamental knowledge of their own biological uniqueness as part of a comprehensive health education program. A life sciences/health education curriculum must be reinforced by consistent school climate and policies, family and community support, constructive messages from the media, and favorable governmental policies -- a far better alternative than continuing the counterproductive practice of allowing society to consistently criticize youth as being the problem itself.

RECOMMENDATIONS

7-38 The President should direct the Secretary of Health and Human Services and the Secretary of Education to co-chair a task force on comprehensive school-based health programs. The task force should articulate concepts which will drive development of a truly comprehensive health education program at the local level. Strategies for funding should also be produced. Additionally, the task force should explore the development of incentives for school systems to incorporate these concepts into their programs. The Elementary and Secondary Education Act Amendments of 1988 (the Hawkins-Stafford bill), which provides funds for school systems to develop coordinated health and physical education programs, is an example of such an incentive.

7-39 All schools, both public and private, should have comprehensive health education programs for grades K through 12 fully implemented by the year 2000.

7-40 School boards and parents should develop means to incorporate values emphasizing personal responsibility in the general education curriculum.

CHAPTER EIGHT: SOCIETAL ISSUES

As the Commission looked at patterns of HIV infection and particularly their correlation to intravenous drug abuse, the relationship between the spread of HIV and longstanding societal problems became apparent. It is imperative that this nation recognize and address the context in which the epidemic is occurring. It is occurring disproportionately within the underclass, the largely minority population of the inner city poor. (For discussion of the "underclass," see William Julius Wilson, *The Truly Disadvantaged -- the Inner City, the Underclass and Public Policy*, the University of Chicago Press, 1987.)

Witnesses before the Commission presented considerable evidence that the occurrence of drug abuse, particularly intravenous heroin abuse, is frequently found in communities where poverty and crime are endemic. It has been noted that persistent poverty in the midst of an affluent society engenders hopelessness and despair which can lead to heroin abuse and related high rates of crime.

In HIV prevalence studies of homosexual men, intravenous drug users, and patients at sexually transmitted disease clinics, inner city areas consistently report the highest prevalence rates, with minorities overrepresented among this population. In addition, witnesses testified that neighborhoods characterized by high rates of teenage pregnancy, high school dropouts, crime (particularly drug-related crime), welfare dependency, males who are jobless, and female-headed households (which represent over 90 percent of households in some urban housing projects) have suffered a high rate of heterosexual transmission.

Heterosexual transmission is occurring particularly in communities where prostitution and drug abuse are prevalent, and where HIV infection is correspondingly high (as high as 70 percent among intravenous heroin users in some areas). In this setting, the disease has dispersed rapidly into the heterosexual community through the sexual partners of those infected. As many as five percent of mothers delivering babies in some inner city hospitals are now infected, a frightening statistic, especially when we consider the social and financial ramifications of a rapidly increasing incidence of pediatric HIV infection. Some of our public city hospitals are already overwhelmed, and we have only seen the beginning of the acceleration of this pediatric HIV crisis.

In addition to intravenous heroin use, crack and cocaine use are likely avenues for the spread of HIV. Witnesses testified that drug users tend to use any available drug and method in pursuit of a "high," underscoring the interconnection of drug-using sub-populations. Evidence from a small number of studies suggests that crack and cocaine users may be at considerable risk for contracting and spreading HIV because they tend to be involved in frequent, indiscriminate sexual activity and prostitution.

A Johns Hopkins University study estimated that unemployment, declines in income, and high school dropout rates are significant national predictors of narcotics arrest rates. Witnesses testified that there is a correlation between inner-city unemployment rates and narcotics arrests. Thus, when the employment rate rises, it could be inferred that drug use and the high-risk behavior which accompanies that drug use, decreases. The connection with HIV infection is apparent.

For those with few skills to offer, the drug economy promotes an alternative model of achievement. If the attraction of the drug economy is to be decreased, then productive alternatives for developing earning potential are necessary.

Intensive efforts are needed to train and place unskilled workers, including rehabilitated drug addicts, and to build their self-respect, confidence, and hope. The employment of these workers is paramount to remedying underclass societal and family problems. Jobs, alternatives to the drug world, and motivation for further education are all needed. A statistic often quoted is that one job provided to a head of household takes four people off welfare and an unknown number out of the prison system. Witnesses before this Commission have repeatedly testified to the cost-effectiveness in both human and financial terms of employment and job training programs.

Lacking health insurance typically provided through employment, individuals living in poverty also suffer from too little medical care and high rates of acute and chronic illness. Although the Medicaid program was designed to be the nation's health insurance program for the poor, Medicaid currently provides health care coverage for only about 40 percent of those with incomes below the poverty line. Management of the HIV epidemic presents additional new problems in prevention and care for a population already receiving inadequate health services.

In addition to inner-city poverty-stricken communities, the 1980's have witnessed an explosion of homelessness in our nation. Between 400,000 and 3 million persons are currently estimated to be homeless. While the HIV infection rate in homeless persons is unknown, witnesses report that many HIV-infected persons may have become homeless because of discrimination as a result of being infected.

It has often been said that a society is judged by how it responds to those in greatest need. A tragedy such as the HIV epidemic brings a society face to face with the core of its established values, and offers an opportunity for the reaffirmation of compassion, justice, and dignity. Many individuals and groups in our society have responded to the HIV epidemic so as to reaffirm these basic values. The development and growth of community-based organizations, particularly in the homosexual community, has been remarkable. The response of many employers, corporations, philanthropies, and religious organizations and institutions has also been exemplary. A further commitment by our society to a response to the HIV epidemic characterized by compassion, justice, and dignity is imperative.

It has been shown that improvements in health and mental health and increased longevity are related to increased per capita income and decreased unemployment rates. Lower crime rates are also positively correlated with increased employment and a higher socioeconomic status.

In a recent study conducted by the Council on Economic Development, leading business leaders recognized that the productive capacity of the nation depends on its people and concluded that unless the needs of children in poverty are addressed, the nation would suffer economic decline and perhaps even social disarray. The study concluded that "the single most important investment the nation can make . . . is to provide comprehensive pre-school preparation for every educationally and economically disadvantaged child in the nation, beginning at conception if not well before."

The Commission endorses this statement and points out that the presence of the HIV epidemic only increases the urgent need to address the problems of poverty, unemployment, teenage pregnancy, drug abuse, and homelessness, and the human suffering and social costs that they generate.

Section I. Drug Abuse and the HIV Epidemic

Our nation's ability to control the course of the HIV epidemic depends greatly on our ability to control the problem of intravenous drug abuse. Intravenous and other drug abuse is a substantial carrier for infection, a major port of entry for the virus into the larger population. Although intravenous drug abusers constitute only 25 percent of AIDS cases in the United States, 70 percent of all heterosexually transmitted cases in native-born citizens comes from contact with this group. In addition, 70 percent of perinatally transmitted AIDS cases are the children of those who abuse intravenous drugs or whose sexual partners abuse intravenous drugs. And the situation is rapidly worsening as the number of infected drug abusers grows daily.

Among the more tragic manifestations of this epidemic are the infected infants of intravenous drug abusers. Most of these children die in their first few years of life. Many never leave the hospital. Their time on this earth begins with a few months of drug withdrawal in an isolation unit and ends after a series of painful illnesses. Because few have visitors in the hospital, the nurses, physicians, social workers, and volunteers who staff our pediatric acute care units become father, mother, and friend to these children. By 1991 there are expected to be 10,000 to 20,000 cases of AIDS among infants and children.

But they represent only the beginning of the tragedy if this nation does not move to address its entire drug abuse problem. The Commission recognizes that alcohol and drug abuse in all their manifestations represent a threat since the use of alcohol or any drug which impairs judgment may lead to the sexual transmission of HIV. The United States continues to have the highest rate of illicit drug use among young people of any country in the industrialized world. Our drug problem pervades all elements of society. A recent study has demonstrated that drug abuse is a problem for both suburbs and inner cities, for all races, and at all income levels. Without a coordinated and sustained response, America as a whole faces a bleak future.

In addition to the devastation that drug abuse represents for the individual, the family, and the community, the purely financial cost of drug abuse -- in terms of providing health care, reduced productivity, law enforcement, plus theft and destruction of property -- is estimated at $60 billion annually. This remarkable figure does not include the staggering costs of providing health care for drug abusers with HIV infection.

A number of efforts to curb drug abuse have been initiated. The First Lady's highly visible "Just Say 'No' " campaign, for example, has successfully drawn our nation's attention to the devastation of drug abuse and called on America's youth to reject drugs. Such efforts need to be strengthened and increased. In addition, more needs to be done in providing treatment for those already addicted.

But curbing drug abuse will require major commitments from many sources. It will require, first, that individual drug abusers take personal responsibility for their own well-being. Treatment systems to be effective require the commitment of individual drug abusers to the treatment regimen. It will also require a major commitment from federal, state, and local governments, as well as parents, educators, and community leaders to work together to initiate new prevention and education programs and to build community support for eliminating drug abuse and drug trafficking.

The Commission's recommendations are designed to develop a comprehensive, ten-year strategy to deal with the nation's intravenous and other drug abuse problems. This will be accomplished by increasing treatment capacity, increasing research into treatment modes, strengthening primary prevention and early intervention programs, and conducting aggressive outreach programs in HIV-related education and prevention. The Commission recommends a system which can accommodate a treatment-on-demand response for intravenous drug abusers.

Provision of Treatment Services

The Commission believes it is imperative to curb drug abuse, especially intravenous drug abuse, by means of treatment in order to slow the HIV epidemic. Because a clear federal, state, and local government policy is needed, the Commission recommends a national policy of providing "treatment on demand" for intravenous drug abusers.

This policy would need to be a long-term commitment, and the funding should come from a 50 percent federal and 50 percent state-and-local matching program. The spending should be accompanied by the institution of a national campaign to promote community acceptance of treatment programs.

Given the fact that temporarily alleviating the health effects of symptomatic HIV infection can cost as much as $100,000 per person and that imprisonment costs an average of $14,500 per person per year, and even without considering the previously cited astronomical costs of drug abuse to the nation, the investment necessary to provide for intravenous drug abuse "treatment on demand" is sound public policy. Current treatment modes for intravenous drug abusers, including methadone maintenance and drug-free residential communities, reduce illicit drug use, improve employment among addicts, reduce crime rates, and improve social functioning.

Obstacles to Progress

The Commission has identified the following obstacles to progress in providing drug treatment services nationwide:

- The National Institute on Drug Abuse (NIDA) estimates that 6.5 million people are now using drugs in a manner which significantly impairs their health and ability to function. Of these, 1.2 to 1.3 million are intravenous drug abusers. At any given time there are probably not more than 250,000 drug abusers in treatment, of whom 148,000 are intravenous drug abusers. The lack of treatment capacity has produced long waiting lists for treatment, in some cases up to six months, in three out of four cities in the United States. During this waiting period many intravenous drug abusers continue to use drugs intravenously several times each day, increasing their risk of contracting and spreading HIV, and in many cases diminishing their resolve to enter treatment.

- Treatment capacity in most parts of the country can be increased by approximately 20 percent with the addition of treatment funds. But further expansion could exceed the capacity of the nation's existing infrastructure and may require an increase in "brick and mortar" funds and a concerted effort to recruit and train more personnel.

- A substantial commitment of funds by federal, state, and local governments, plus private care providers, is needed to expand expeditiously the quantity and improve the quality of the treatment system. Further, collaboration among all these sources is needed to design innovative plans for reducing barriers to expansion. This expansion should incorporate treatment models which have been demonstrated to be cost-effective. As an interim emergency measure, it may be necessary to establish minimal service or "holding" clinics, but as soon as possible patients must be admitted to programs with full services, including psychological counseling and medical care.

- Rates of effectiveness of treatment are directly related to retention in treatment. Attention must be paid to improving the quality of treatment to retain clients until they are rehabilitated.

- The presence of HIV infection in the drug-abusing population has generated a decline in the overall health of this population, with dramatic increases in deaths from bacterial pneumonia, tuberculosis, endocarditis, nephritis, and a variety of other infections.

- Establishment of community-based treatment programs has been hampered by the "not-in-my-neighborhood" syndrome.

- Many community services which could give much needed support to clients in drug treatment programs are not well coordinated.

- The treatment field needs more trained staff and in-service training. HIV infection has increased the already heavy burdens on those in this field. In addition to their regular duties, they now face the need to educate their clients on HIV-related issues, risk reduction activities, and, in many cases, the psychosocial needs of dying clients.

- The special needs of women of childbearing age have become more pronounced, emphasizing the need for programs for addicted women, addicted pregnant women, and their children.

RECOMMENDATIONS

In response to these obstacles, the Commission recommends the following improvements in providing drug abuse treatment, with emphasis in every instance on appropriate HIV-related education and prevention:

8-1 In the near term, the National Institute on Drug Abuse, in conjunction with state agencies, local drug abuse officials, and representatives of drug treatment providers, should develop a plan for increasing the capacity of the drug treatment system so that the goal of treatment-on-demand can be met. The plan should designate an implementing office with the staff and technical capacity to guide implementation of the plan. The plan should provide for matching funding on a 50 percent federal and 50 percent state-and-local basis. It should have elements for a phased, targeted increase in programs insuring the quality of care and mechanisms to evaluate progress and make appropriate adjustments.

8-2 The Alcohol, Drug Abuse, and Mental Health Block Grant program should continue to be the mechanism for disbursing treatment funds. However, provisions must be made for expediting disbursements and targeting the money to those areas with the largest numbers of intravenous drug abusers. If using the block grant mechanism would cause undue delays in accomplishing this, consideration should be given to such methods as state and citywide contracts that could later be folded into the block grants.

8-3 The Alcohol, Drug Abuse, and Mental Health Block Grant funds should be directed to activities that stimulate and help patients to enter the treatment system. These activities should include, but not be limited to: aggressive outreach services to drug abusers; telephone hotlines that provide treatment information and initial access to treatment programs; centralized assessment, referral, or intake units; linkages between drug abuse programs and community service agencies, criminal justice and correctional systems, employers, schools, churches, clinics for treatment of sexually transmitted diseases, prenatal clinics, mental health professionals, marriage, family, and sexual counselors and therapists, hospice care, HIV crisis networks and coalitions; and mechanisms for identifying, developing, and cataloguing treatment resources within the community.

8-4 Federal constraints on funds for constructing, expanding, and renovating facilities for intravenous drug treatment should be made more flexible in response to increased treatment needs. In addition, a wide range of federal and local financing arrangements for community-based treatment programs should be considered.

8-5 Since an estimated 1.2 million intravenous drug abusers are concentrated in 24 cities in the United States, treatment should be quickly expanded in those cities by having state, city, local, and community officials identify facilities which could be used for treatment centers. These should include hospitals, clinics, and other health-related sites. Approximately 2,500 new facilities may need to be developed this way.

8-6 As an interim step until new treatment facilities can be developed, state drug abuse agencies should consider contracting with allied health professionals and social workers or organizations to serve as case managers for drug abuse clients. Case managers, who need not be affiliated with traditional drug abuse facilities, could procure medical, educational, job training and social services, and other necessary services, from existing community resources. They could assess client needs, develop individualized treatment plans, procure services, and monitor service delivery. The federal government should provide demonstration funds for projects that use the case management approach to bring external community resources into treatment plans.

8-7 The National Institute on Drug Abuse should develop model demonstration programs that are community-based. These should focus on ethnic and minority populations that have been disproportionately affected by the HIV epidemic, and on the treatment needs of teenaged intravenous drug abusers. In addition, grants should be made to communities which are designing and implementing treatment programs that integrate community services and have the support of community leaders.

8-8 More emphasis needs to be placed on matching treatment with the specific needs of clients. Drug addiction is a disease of the whole person involving multiple areas of function. To be effective, any treatment approaches must ultimately address many dimensions of the client. Those who fund and administer treatment programs should become more flexible, focusing not only on drug abuse behaviors, but also on other dimensions of the client's life (e.g., educational and vocational deficiencies and family problems) that may contribute to drug abuse. Services should not be limited to those that can be provided within a program's own facilities or by its own staff. There should be more extensive use of services available in local communities which can help to rehabilitate the drug abuser. This will require a focus on continuity of care, whether services are provided in one facility or in a number of community facilities. Community care facilities which receive public funds should be required to coordinate services with drug treatment programs and should be monitored by appropriate authorities.

8-9 Treatment programs should try different strategies to encourage patients to participate. These should include: extended hours of operation, operation during unusual hours, mobile treatment units, 24-hour satellite clinics in medical facilities, and storefronts in communities. Results of these efforts should be carefully evaluated.

8-10 Effective drug treatment, especially in this HIV epidemic, includes dealing not only with the health care needs of patients but also of their families. Treatment should include on-site primary services or referrals to community health centers, mental health centers, and other accessible community-based resources.

8-11 Comprehensive programs should be made available for women who are intravenous drug abusers and are of child-bearing age, pregnant, or mothers.

These programs should provide treatment as well as prenatal and postnatal care, day care facilities, family planning, HIV testing, counseling, and child welfare services. It is essential that these services be provided during extended hours.

8–12 Drug treatment programs must aggressively provide HIV prevention and risk reduction education to clients and their sexual partners. Information must be provided on the dangers of needle and paraphernalia sharing, the immunosuppressive effect of drugs (including nonintravenous drugs and alcohol), sexual transmission, and risks to the unborn. Voluntary HIV testing should be strongly encouraged for clients, their sexual partners, children of intravenous drug-abusing mothers, and children of sexual partners of intravenous drug abusers. Any such testing must be accompanied by a counseling program. Collaborative efforts should be established to routinely refer released prisoners to drug treatment programs near their homes, for HIV services as well as drug intervention, if such prisoners are known to have a history of drug use.

8–13 Political and community leadership should be exerted to reduce barriers to the establishment of community treatment facilities in appropriate locations. In communities where there are high rates of drug abuse and a proven need for drug abuse rehabilitation programs, but continued resistance to their establishment, health commissioners should review the possibility of invoking emergency health measures to overcome this inertia and resistance.

8–14 Quality assurance in drug abuse treatment programs needs to be reexamined. Quality of care needs to be better defined by the drug abuse treatment field and standards for programs and practitioners need to be established or refined. States should reexamine their licensing procedures for drug abuse treatment programs. The federal government should support studies of treatment outcome and the development of scientifically based quality assurance mechanisms.

8–15 A significant increase in trained personnel will be needed to implement new programs. Approximately 59,000 persons will be needed to join the ranks of drug abuse workers. New staff training programs should be developed at universities, community colleges, vocational and technical schools, and through internships in existing drug programs and the training of ex-addicts. Curricula dealing with education, prevention, and treatment of substance abuse and HIV should be developed throughout the educational systems for physicians, nurses, and social service workers. Federal leadership is needed to foster and identify model curricula for training programs as well as establishing the fields of drug abuse prevention, treatment, and research as viable and rewarding professions.

8–16 Staff development and training for drug abuse treatment providers must include education and skill development related to HIV, such as education in the modes of HIV transmission and prevention.

8–17 State judicial and correctional systems should consider assigning individuals to drug treatment programs as a sentence or in connection with sentencing. For persons convicted of drug-related offenses or those convicted on non-drug-related offenses but found to be drug abusers, the convicted person should be placed in a drug treatment program in those instances where probation authorities recommend alternatives to imprisonment. To assure program compliance, the convicted person should serve a prison sentence for violating the terms of the drug treatment program. Those who are incarcerated should be referred upon release to drug treatment facilities near their homes.

Treatment Research

The Commission's research has led us to conclude that improved and expanded research focusing on intravenous and other forms of drug abuse and HIV will require a long-term commitment. Funding priorities should follow guidelines set forth below.

Obstacles to Progress

The Commission has identified the following obstacles to progress in treatment research:

- Intravenous cocaine use has been increasing in the United States and, while there are pharmacological treatments for intravenous heroin use, there are no such proven pharmacological agents for intravenous cocaine use.

- Efforts to be innovative in treatment have not been aggressive. There have not been enough experiments with new procedures and model treatment program development.

- Due to inconsistent funding, treatment researchers have often sought other more stable fields in which to work.
- Grant and contract cycles are often too drawn out to cope with the urgency of the HIV epidemic.
- Data on drug abusers are not being collected in the uniform way that might provide the basis for responsive policy decisions.

RECOMMENDATIONS

In response to these obstacles in treatment research, the Commission recommends the following:

8–18 The National Institute on Drug Abuse should expand its comprehensive research program. It should particularly emphasize strategies for the treatment of intravenous cocaine use.

8–19 The National Institute on Drug Abuse should sponsor additional research to determine which clients will most likely succeed in a particular treatment program.

8–20 The National Institute on Drug Abuse should sponsor additional research in improved pharmacological agents for drug abuse treatment, including narcotic antagonists, mixed agonist-antagonists, non-pharmacological strategies and more effective delivery systems.

8–21 The National Institute on Drug Abuse should fund research to improve service delivery, treatment methods, and innovative types of treatment. Results should be disseminated to the field.

8–22 Federally sponsored research should be conducted on the effects of drug abuse on the immune system in order to determine the efficiency of HIV transmission to and from drug abusers and to prevent asymptomatic HIV-infected individuals from progressing to symptomatic disease.

8–23 The grant processing cycle must be shortened throughout government to provide quicker review and approval of applications for grants related to HIV research in general, and in particular as it relates to drug abuse research in data collection, demonstration programs, prevention and treatment research.

8–24 Studies funded by the National Institute on Drug Abuse should be undertaken expeditiously to provide adequate data on the number of drug abusers, the number in treatment, the HIV rates among drug abusers, and baseline research into the sexual patterns of drug abusers. The data can be used to promote detailed planning by the federal government, states, cities, and communities. Also needed is research that examines the characteristics of addicts which lead them to respond to various social and environmental pressures. Since success rates in treatment are related to length of stay in treatment, research should continue on ways to improve retention in treatment.

Drug Abuse Prevention

Primary or overall drug abuse prevention requires the sustained efforts of parents, educators, community leaders, and all levels of government, collaborating to develop effective new prevention approaches and expand existing prevention programs. Community organizations, religious institutions, and schools should be encouraged to design value-oriented educational programs to discourage drug abuse and to encourage rehabilitation.

Obstacles to Progress

The Commission has identified the following obstacles to progress in implementing drug abuse prevention:

- Prevention strategies need to be evaluated over long periods of time. Such a process is complicated by the many factors influencing human behavior, which slow analysis of the effectiveness of various strategies and slow even more the dissemination of model programs.
- Funding for prevention research has not always been consistent, leading researchers to migrate out of the field and leading to uneven productivity of the research effort.
- Presenting a consistent message is fundamental to eliminating confusion about drug abuse among children. It is essential to coordinate efforts linking school to community to religious institutions to family to individual; yet such coordination is sporadic at best.
- Not enough attention is being paid to providing effective model programs and training community groups in effective prevention programming.

RECOMMENDATIONS

In response to these obstacles, the Commission recommends the following:

8–25 The Alcohol, Drug Abuse, and Mental Health Administration's Office of Substance Abuse Prevention should sponsor more research into the root cause of drug abuse, determination of those at greatest risk, and the most effective means of preventing drug abuse.

8–26 The federal effort should emphasize the development, implementation, and evaluation of model prevention programs with aggressive dissemination of effective models. Current knowledge of effective prevention and intervention strategies, such as those based on the significant influence of family and peers, should be used in developing additional prevention programs.

8–27 To the extent that current research provides the tools necessary to identify young people at risk for drug abuse through their behaviors, the Office of Substance Abuse Prevention should make this information, as well as proven intervention techniques, widely available through publications, conferences, training sessions, and a national clearinghouse.

8–28 Educators should design and offer training courses on drug abuse prevention and intervention at both the undergraduate and graduate levels as well as programs to train specialists with the expertise needed to develop and implement drug abuse and HIV prevention efforts in ethnic minority communities. Special training should be designed for health professionals and alcohol and drug counselors, and should include the latest information on prevention of high-risk behaviors.

8–29 State and local drug agencies should support community plans to identify and develop human resources within minority communities for the drug abuse and HIV intervention effort and implement them on an urgent basis.

8–30 The federal government should support regional workshops to provide educators, parent groups, voluntary organizations, and community leaders with skills to conduct effective prevention programs to meet local needs.

8–31 Community and parental involvement should be sought in community-wide drug abuse programs. Developing public commitment to the elimination of drug trafficking should be an integral part of this effort.

8–32 Innovative community-based prevention programs should be implemented, such as culturally significant and current modes of communication, like "Rap" contests on preventing drug abuse and HIV, and peer youth training aimed at preventing initiation into the drug culture.

8–33 Current information and prevention strategies should be used widely within our education systems and communities to create an atmosphere which promotes drug-free lifestyles. Educational materials and prevention strategies must be age-appropriate and culturally relevant.

8–34 The media should be urged to donate air time for appropriate messages on drug abuse and HIV. Additionally, programming should include accurate messages on the consequences of drug abuse.

8–35 The Department of Housing and Urban Development, in conjunction with state drug abuse agencies, should give special attention to public and other low income housing in creating a drug-free environment for youth. Communities in public housing that want to establish drug abuse prevention programs should be offered the organizational support of drug abuse prevention specialists and funding to support drug abuse education and prevention campaigns.

8–36 Schools, churches, and religious institutions should be encouraged to design appropriate value-oriented educational programs to discourage drug abuse and to encourage rehabilitation.

Outreach Education

Although education is one component of an outreach effort that should be an ongoing and persistent process, it alone cannot necessarily change behavior. Targeted information, coupled with intervention and treatment, is more likely to produce the desired behavior change.

Obstacles to Progress

The Commission has identified the following obstacles to progress in providing outreach education:

- Because drug abusers are engaged in illegal activity, they are frequently alienated from society and therefore more difficult to reach through the usual education channels. However, contrary to common belief that intravenous and other types of drug users do not care about their health, outreach efforts thus far have identified concern among drug users about HIV infection and a willingness to change behavior in order to reduce the risk of infection.

- Currently, much needed outreach is being conducted in high-incidence areas; as that work continues and is expanded, low-incidence communities must not feel any sense of complacency. There is little time from the introduction of HIV into a drug-abusing population to the increase of the prevalence of the infection in that community. Action must be taken in advance to prevent the spread of the virus.

- In reaching drug users, the most effective technique demonstrated so far has been the use of indigenous street outreach workers, often ex-addicts, who are recruited and given intensive training on HIV and its spread. Many more of these trained outreach workers are needed. They should be provided with written material to distribute and should initiate conversations with drug users near shooting galleries and other places frequented by drug users, engaging in one-on-one communication and education.

- Outreach workers who meet with drug abusers and discuss risk reduction report that the drug users ask for treatment. Unfortunately, with nationwide waiting lists, outreach workers too often do not have treatment to offer. This leaves addicts who are ready to receive help with virtually no options.

- With 70 percent of the perinatally transmitted pediatric HIV patients being the children of intravenous drug-abusing women or women whose sex partners are intravenous drug abusers, these women are at increased risk and need many specialized services, which today are in extremely limited supply.

- Many minority communities face disproportionate rates of HIV infection; too few targeted outreach programs are currently being designed and implemented for these communities.

- Verbal, one-on-one communication within the minority communities appears to be the most effective way to communicate health messages. We solicit the help of religious institutions to reach this population. Television and radio can also be effective if appropriate assessments are made of peak viewing and listening times.

RECOMMENDATIONS

In response to these obstacles in outreach education, the Commission recommends the following:

8-37 The National Institute on Drug Abuse should sponsor additional research to determine which techniques are effective in producing behavior change among intravenous drug abusers. Particularly needed is research examining the most effective ways of educating ethnically and culturally diverse groups. Since time is critical, research must take place in conjunction with the institution of programs.

8-38 While drug-using populations in high HIV-prevalence regions are targeted, those communities in low-incidence areas should recognize the threat of HIV spread and encourage drug users to seek treatment. While treatment has proven effective in reducing the rate of spread of the HIV, the spread will not be stemmed without intervention in both low- and high-incidence communities. Outreach programs to the drug-abusing population should therefore be expanded in both high- and low-incidence areas. In addition, communities with low HIV prevalence rates in their intravenous drug-using population should engage in prevention and education campaigns to keep those rates low.

8-39 State and local drug abuse agencies should expand the treatment system and outreach efforts together. Outreach workers must have treatment programs available to offer drug users who are willing to take action. Education without treatment is empty.

8-40 Programs aimed at prevention, intervention, and rehabilitation among intravenous drug users should include outreach to their sexual partners. All providers of care in substance abuse programs should be enlisted in efforts to prevent sexual transmission of HIV.

8-41 Creative outreach programs should be implemented to reach drug users and adolescent runaways in homeless shelters, shooting galleries, hospitals, and other places where addicts congregate. Innovative outreach techniques should be used, including such ideas as the distribution of coupons to be redeemed for drug treatment and the use of mobile vans. One-on-one communication should be supplemented by flyers, posters, and other creative means of presenting information.

8-42 Outreach efforts should have an HIV prevention and risk reduction emphasis, focusing on the risks associated with needle- and paraphernalia-sharing as well as sexual and perinatal transmission.

8-43 Training of street outreach workers and of staff should be continued and expanded. Ex-addict street educators should be integrated with community-based treatment staffs who are familiar with the communities where they work and reflect the ethnic composition of the communities.

8-44 Prevention programs for minorities should be established at the grass roots level and on a one-to-one basis with peer contact, in shooting galleries and in neighborhoods. The information presented must be understandable, culturally sensitive, and direct. Ethnic minorities should be included in the planning, developing, and implementation of such efforts.

8-45 Outreach efforts should be targeted at female intravenous drug users and females of childbearing age who are sexual partners of intravenous drug users. All providers of women's health care should be enlisted in efforts to prevent sexual transmission of HIV. Most women who visit a women's health care provider, whether it be for family planning or a routine checkup, have no other health contact annually.

8-46 All women's health care providers, in providing pregnancy and maternity services, should make maximum effort to avoid increasing the risk of infection of neonates by infected pregnant women.

Supply of Illegal Drugs to the United States

The dangers and costs of drug abuse have taken on a new dimension, a greater horror, because of the relationship between HIV infection and drug use. Recent efforts to control the use of illegal drugs have demonstrated the importance of addressing both the demand for drugs and the readily available supply of drugs in our society. Along with many others, the President's Commission on Organized Crime has pointed out the ". . . dual nature of the drug phenomenon: drug supply and drug demand are mutually dependent aspects of a single global problem."

Our young people are lured into drug abuse by the ready availability of illicit drugs. For those who have few alternatives in life, dealing in drugs offers "easy" money and a luxurious lifestyle, leading to drug trafficking and other crimes. It is imperative that we break that chain by reducing simultaneously both the supply of drugs and the demand for drugs.

Illegal drugs are readily available on our streets for those who want to buy, from both domestic and imported sources. Marijuana is a leading cash crop in some areas of this country, undermining our efforts to persuade foreign governments to eradicate crops in their countries. An estimated 3,000 shipments of illegal drugs enter this country each day. Despite a record number of seizures, more cocaine is coming into this country each year (in 1987 the Drug Enforcement Agency seized almost 79,200 pounds), its price is decreasing, and cocaine use is increasing. Stopping the flow of drugs into this country must be addressed at both the source in foreign countries and at our borders. The Commission supports current efforts to strengthen international narcotics control through bilateral and multilateral agreements, development assistance, and collaboration with foreign governments on training programs for foreign officials, crop eradication, and law enforcement activities. At the same time, detection of drug smugglers must be augmented by increased surveillance of ships and planes carrying drugs into the United States and strengthened law enforcement by federal agencies. The unique capacity of the military and National Guard should be appropriately utilized in partnership with domestic drug enforcement agencies.

In conjunction with the fight against drug smuggling, a strong effort to reduce the domestic drug supply must also be launched. Cultivation of marijuana crops and laboratory production of dangerous drugs such as PCP must be curbed. To create a realistic deterrent to drug abuse, harsher penalties should be imposed both on those who sell drugs and those who buy and use drugs. Enforcement of drug laws at the state and local levels should be increased with stiffer sentences, larger fines, and forfeiture of assets derived from drug trafficking. Judges must recognize their obligation to support responsible law enforcement.

Strengthening law enforcement against illicit drug trafficking and drug use will create new needs in an already overburdened criminal justice system, and require additional courtroom personnel and facilities and more jails and prisons.

The Commission recognizes that the task of formulating strategic drug control planning and policies falls principally on others whose focus is directed toward those ends. However, numerous experts at the federal, state and local levels testifying before the Commission emphasized repeatedly the multiple complexities of the drug problem and the strong correlation between the demand for and the supply of drugs. The fight to end drug abuse in America calls for the integration of education, prevention, treatment, enforcement, prosecution, and corrections. This Commission must act to enhance efforts in all these areas. The magnitude of the threat for the spread of HIV infection posed by the current levels of drug abuse is too great for this Commission not to take some responsibility for finding solutions to the supply aspect of the drug problem.

Obstacles to Progress

The Commission has identified the following obstacles to reducing the supply of illicit drugs in this country:

- Exorbitant demand for drugs by Americans from diverse economic backgrounds.
- Inadequate deterrence in existing drug laws.
- Huge profits in marketing of illegal drugs which eases recruitment of youngsters into peddling drugs and leads to drug-related crime.
- Reported rivalries and lack of cooperation among law enforcement agencies at the federal, state, and local levels which sometimes hampers coordinated, broad-based action against drug traffickers.
- Limited resources in the criminal justice system leading to lack of trained and experienced personnel, both investigative and prosecutorial; inadequate jail space; and overcrowded prisons.
- Tolerant attitude toward drugs by courts, legislatures, and the community in general; lenient sentencing by judges.
- Resource constraints of drug supply countries.
- Lack of alternative lifestyles for those in poverty.
- Very extensive and open movement of people across United States borders. Approximately 6.5 million people per year apply for tourist visas in the United States, with approximately 300 million border crossings between the United States, Mexico, and Canada.
- Casual attitude about the serious repercussions of breaking the law.

RECOMMENDATIONS

The Commission believes we should persevere in our efforts to develop a comprehensive approach to eliminating the traffic in illicit drugs. Specifically, the Commission recommends:

8–47 State and local governments should make illicit drug control a high priority and provide adequate funds for drug-related programs. Increased funding should be provided for additional law enforcement personnel, prosecutors, judicial resources, and prisons.

8–48 State and local governments must strengthen their drug abuse laws and regulations and increase their enforcement. In addition to strengthening programs to reduce the supply of illicit drugs, individuals and community organizations should establish strong anti-drug policies aimed at reducing the demand for drugs. For example, schools and colleges and universities must establish and enforce strict anti-drug policies and procedures for students, teachers, administrators, and staff. All private and public employers, including transportation organizations, should have a strong anti-drug work policy applicable to all employees.

8–49 States should enact stronger penalties for those convicted of selling, possessing, and/or using drugs, including, where appropriate, minimum mandatory sentences. Individuals on probation or parole from drug sentences should have probation or parole revoked upon violation of the conditions of their release, especially where those violations are drug-related.

8–50 State and local governments should develop programs aimed at parents of minors convicted of drug-related offenses, including elements such as training courses and community service requirements.

8-51 The process for confiscating, liquidating, and distributing the assets of drug sellers and users must be enhanced:

- The Federal Bureau of Investigation and the Drug Enforcement Administration must hire and train more forfeiture specialists to ensure more expeditious review of seizures.
- All states should enact asset seizure and forfeiture statutes.
- Greater effort must be made to protect seized assets in custody to ensure that assets retain their maximum value.
- Consideration should be given to permitting, under certain circumstances, asset forfeiture funds to be disbursed for capital expenditures related to drug control operations.
- With respect to the sharing of funds generated by forfeited property pursuant to statutory provisions, consideration should be given to expanding the scope of such equitable sharing provisions to permit sharing by foreign government law enforcement authorities assisting in United States government drug control operations.

In addition to the above recommendations, the Commission strongly endorses other drug control efforts, many of which are currently underway. In endorsing these programs we recognize that some may have significant cost implications. However, we will leave the cost benefit analysis of these programs to those more directly involved in the process of implementing the programs. Accordingly, the Commission strongly endorses the following:

- The National Drug Policy Board should continue its efforts to coordinate the programs of federal agencies involved in the enforcement of drug control laws. The budget, resources, and operations of the involved agencies should be coordinated to the fullest extent possible to achieve the most efficient use of available resources and avoid duplication and waste.
- Consistent with both established worldwide commitments of United States military forces and targeted appropriated funding, the Department of Defense (DoD) should continue to provide, and on a sustained basis for the foreseeable future, military support to the national effort to stem the supply of drugs. DoD should regularly advise law enforcement officers of DoD capabilities to assist in the drug supply effort and facilitate the process for responding to requests for assistance.
- The Drug Enforcement Agency (DEA) should strengthen the coordination of all state, local, and federal eradication initiatives. DEA should continue working with the states to develop new programs to eradicate illicit crops and laboratories and through the State Department to expand efforts to convince governments in countries where drugs are grown to develop and enhance eradication programs.
- The Customs Service and the Coast Guard should have access to the most sophisticated detection equipment and boats and airplanes to carry out maritime and air interdiction missions.
- Aggressive enforcement of the criminal justice provisions and international narcotics control provisions of the Anti-Drug Abuse Act of 1986, and full funding of the provisions relating to drug law enforcement should be continued and strengthened.
- Collaboration between federal, state, and local law enforcement agencies in carrying out drug control policies to maximize the impact of the federal plan within every jurisdiction in the country should be continued and strengthened. Drug control policies need to be comprehensive and need to emphasize the importance of sustained efforts by interdiction and law enforcement agencies.
- Expansion is needed of Department of Justice (DOJ) assistance to state and local narcotics enforcement programs, including technical assistance in drafting of state legislation on money laundering, drug conspiracy based on the Federal Racketeer Influenced and Corrupt Organizations provisions (RICO), electronic surveillance, forfeiture, enhanced penalties, and grand jury powers. Also, enhancement of DOJ training programs for state and local investigators and prosecutors should be undertaken. In addition, DOJ sharing of intelligence information, technical and laboratory facilities, and non-English language support teams with state and local governments should continue.
- Federal, state, and local prosecution authorities should develop programs to provide incentives to recruit, retain, and, where necessary, relocate experienced prosecutors to handle drug-related cases.
- Leadership by district attorneys is needed in the development and implementation of comprehensive community wide anti-drug programs in addition to aggressive prosecution policies and practices.

Section II. Homeless Persons with HIV Infection

The increasing number of homeless persons with HIV infection -- and homelessness in general -- is a serious problem for which there are few simple solutions. Estimates of the size of America's total homeless population vary widely, from 400,000 (National Bureau of Economic Research) to three million (National Coalition for the Homeless). Reasons for homelessness also vary, but common causes include rising housing costs, falling wages, cuts in services to the mentally ill, and, most significantly for persons with HIV infection, discrimination.

In general, the homeless in America can be divided into three groups, all vulnerable to the spread of the HIV epidemic. Approximately 40 percent are chronically and severely mentally ill, receive no treatment while they live on the streets, and are subject to total health care deprivation, multiple infections, alcohol and drug addiction, and physical abuse. The fastest growing segment are poor families, whose principal wage earner has become jobless or has low-paying work. These families now account for one-third of the homeless population. The largest homeless group is comprised of single men, of whom approximately 30 percent are veterans. Many have been on the streets for several years, have become desocialized, and have drug habits or criminal histories. These are all difficult populations to reach, and persons with HIV infection in each of these groups require a stable environment in which to live, access to medical care, and education about transmission.

Two types of housing for homeless persons with HIV infection currently exist and both are in critically short supply: temporary overnight shelters and congregate living facilities that provide a permanent residence. An increasing number of HIV-infected persons stay in municipal shelters on a night-to-night basis and are required to leave during the day. For these persons in particular, access to medical care is almost non-existent. Individuals often hide their illness because discovery may mean physical and psychological abuse, or because once diagnosed, they are no longer eligible for shelter residency. In many instances, once admitted to a hospital, a homeless person cannot be released until he has a permanent address, and shelters do not qualify as official residences. Testimony before the Commission indicated that too often homeless persons with AIDS and HIV-related diseases die in the streets, having found the health care system too difficult to enter or too unresponsive to their special needs.

Persons with HIV infection may become homeless when job discrimination or the debilitating effects of the disease result in inability to work and inability to continue paying medical insurance premiums, medical bills, or rent. Witnesses before the Commission have told of being unable to obtain rental assistance and being abruptly evicted by landlords, primary tenants, or, in some instances, relatives and roommates. Testimony stated that one woman had returned from a stay in the hospital only to find herself locked out of her apartment and her belongings on the sidewalk.

Housing for homeless persons with symptomatic HIV infection is even more limited than for the general homeless population. The person with HIV infection and a damaged immune system cannot survive for very long living on streets, in subways, or city parks. Even in shelters, he or she may be exposed to infectious diseases that could prove life-threatening. Among the general New York City shelter population, for example, tuberculosis has risen at an alarming rate. The housing prospects for homeless HIV-infected women with children are even more bleak.

Adolescents who live on the streets are another homeless problem directly tied to the spread of the HIV epidemic. Many of these children work on the streets as prostitutes in order to pay for food or to support a drug addiction. Organizations that assist runaway youth provide much needed protection for these adolescents, but the problem is greater than the supply of help, and prevention messages are often too late. Dr. James T. Kennedy, Medical Director of Covenant House in New York, testified before the Commission that in a recent study of his adolescent clients, 40 percent were already HIV-infected.

The housing crisis for homeless persons with symptomatic HIV infection is greatest in our large cities, which are unable to deal with their general homeless population, and are unprepared, in terms of resources, to respond to the new problem of homeless persons with HIV-related diseases. While it is difficult to establish concrete estimates of the size of the population of homeless persons with HIV, one study estimated that as many as 1,000 to 2,000 HIV-infected people reside nightly in New York City shelters. Mr. Peter Smith, President of the Partnership for the Homeless Inc., testified before the Commission that: New York City has no separate emergency housing shelter facilities for persons with HIV-related illnesses; the rental assistance program is inadequate; only 18 scatter-site apartments are now available for persons with AIDS; the only specialized homeless facility for persons with HIV-related illnesses, Bailey House, has 44 units; and plans for renovating city-owned abandoned buildings have not been pursued.

Federal Housing Programs

The United States Department of Housing and Urban Development (HUD), the primary source of federal funds for developing such housing, provides funds for both permanent and temporary housing. In 1987, Congress enacted the Stewart McKinney Homeless Assistance Act, and provided five programs to be administered through HUD for homeless relief. Of most direct potential benefit to homeless persons with HIV-related illnesses is the Transitional Housing Demonstration Program, funded at $70 million last year and $49 million this year. This program is intended to fund innovative approaches to develop housing services for homeless persons who are capable of making a transition to independent living.

Another program, entitled the Section Eight Moderate Rehabilitation Program, assists communities in the rehabilitation of single-room occupancy dwellings. Under this program, private funds pay for renovation work, and HUD funds are used to provide rental assistance to low-income households so that the property owner can repay the loan for rehabilitation work. In December 1987, HUD awarded $35 million to 19 public housing agencies to develop over 1,000 units of this housing through the rent collected. A representative from HUD, testifying before the Commission indicated that one project recipient is the Phillips Hotel in San Francisco, which will provide 33 single-room occupancy units in a structured living environment for people with various stages of HIV infection. This project will also provide concentrated support, counseling, and health services.

Community Development Block Grant funds can also be used by states and localities for housing programs. HUD distributes nearly $3 billion a year on a formula basis in this program, with approximately $165 million being used for homeless shelters over the last few years.

Housing assistance was provided to a total of four million households nationwide last year. Central to HUD's current housing assistance program for permanent housing is the distribution of rent certificates and vouchers. This assistance is currently given to one million households. Single non-elderly persons are usually given a low priority for such vouchers, but handicapped persons are given a higher priority. Persons with HIV infection may or may not qualify for a higher priority rating, based on local regulations.

Mortgage insurance for the development or renovation of intermediate or long-term care facilities is available under the National Housing Act through provisions in Section 232. To date, HUD has not received any quantity of applications oriented to HIV-related services, and there is serious doubt that such applications would be funded since a key consideration is whether or not there will be adequate income to pay off the mortgage. Only four states have Medicaid payment levels for persons with HIV that approach the level of reimbursement necessary to make the development of boarding homes or intermediate care facilities for persons with HIV-related illnesses financially feasible.

Medical Care for the Homeless

The Health Resources and Services Administration (HRSA), in the Department of Health and Human Services (HHS), provides medical assistance to homeless persons with HIV-related illnesses through the following programs:

- The Bureau of Health Care Delivery and Assistance (BHCDA) is responsible for implementing the health care provisions of the Stewart McKinney Homeless Assistance Act. This Act calls for the provision of primary care, substance abuse and mental health services to the homeless population. BHCDA granted a total of over $44 million to 108 organizations, primarily Community Health Centers, to provide such care. Any provision of care for substance abuse also implies HIV educational and prevention activities.
- The Bureau of Maternal and Child Health and Resources Development (BMCHRD) is responsible for the educational and prevention activities as well as grant support to communities for HIV services. The budget for these efforts for FY 1988 is approximately $25 million. All AIDS demonstration projects include intravenous drug user program components. Since a large proportion of the homeless use intravenous drugs, this linkage ties together the homeless and HIV intervention activities.
- BHCDA has awarded grants to 43 community and migrant health centers totaling $2 million for the integration of substance abuse recognition, diagnosis, referral and follow-up activities. While no direct linkage was mandated with HIV

initiatives, the drug abuse/HIV relationship and the homeless/drug abuse relationships are clear.

- A joint project between HRSA and the National Institute of Mental Health (NIMH) is just beginning to get underway. This $400,000 project will fund:
    - training programs for homeless youth shelter staff;
    - an ethnographic study of what is currently being done in adolescent HIV prevention projects;
    - development of model policy guidelines for adolescent facilities;
    - regional meetings to address assistance of street youth who become infected or are symptomatic with HIV disease; and
    - technical assistance to communities.

Obstacles to Progress

- An accurate estimate of the size of the homeless population of persons with HIV infection is lacking.
- Seroprevalence studies have not been done on this difficult-to-track population. An adequate assessment of the size and scope of the problem of homelessness of persons with HIV infection is necessary to target future resources.
- Individuals with HIV infection may receive low priority ratings for housing subsidies due to local regulations.
- Construction of shelters or group residences for persons with symptomatic HIV infection has not kept pace with demand in many cities.
- Municipal shelters are unable to diagnose HIV infection or target medical resources to HIV-infected persons in shelters.
- Hospitals are often unable to discharge medically stable homeless patients because they have no permanent street address.
- Service needs of special populations, such as adolescents and women with children, have not been defined or estimated.

RECOMMENDATIONS

8–52 Federal anti-discrimination protection for persons with disabilities, including persons with HIV infection, should be expanded to cover housing that does not receive federal funds. The Department of Housing and Urban Development (HUD) should clarify that Section 504 of the Rehabilitation Act currently prohibits discrimination against persons with HIV infection if federal funds are involved. HUD should actively enforce Section 504.

8–53 The Department of Housing and Urban Development funding for homeless assistance programs should be increased, and funds should be made more easily available to cities and private sector organizations to build both temporary shelters and permanent residences for homeless persons with HIV infection.

8–54 Operators of all homeless shelters and residences must treat those clients who are HIV-infected in an anti-discriminatory manner, protect them from abuse, and help them seek medical assistance as needed.

8–55 The Centers for Disease Control should fund and coordinate targeted seroprevalence studies (e.g., on adolescents, women, and adult men) to be conducted by city agencies in high prevalence cities to establish the size of the homeless population of persons with symptomatic HIV infection and to help cities determine the need for services. In addition to HIV antibody status, these studies should gather information on concurrent medical problems, such as tuberculosis and drug addiction, to both collect cofactor information, and determine the need for greater medical intervention in municipal shelters. Study results including geographic breakdowns should be made available to national mayors' associations, to the Association of State and Territorial Health Officials, and to state and local officials, as appropriate.

8–56 The joint project between the National Institute of Mental Health and the Health Resources and Services Administration on adolescent homeless youth and HIV infection should be expanded and funding increased. More programs on homeless youth should be funded.

8–57 The Department of Housing and Urban Development should provide renovation grants to public hospitals to convert underutilized acute care beds into long-term care beds for HIV-infected individuals requiring hospice or other long-term care.

8–58 The use of the Department of Housing and Urban Development funds to help finance construction and improvement of nursing homes and related facilities should be encouraged to make additional long-term care and hospice care beds available.

8–59 The Veterans' Administration should conduct a short-term study to determine the extent of homelessness among veterans, and HIV infection in this population. The results of this study should be forwarded to the Secretaries of Housing and Urban Development and Health and Human Services for future resource allocation.

Section III. Infants and Children with HIV Infection

There has been a recent, disturbing rise in pediatric AIDS cases, with 85 percent of the total cases reported since 1985. Through June 6, 1988, of the total of 64,506 cases of AIDS reported to CDC, 1,013 have been infants and children under the age of 13 at the time of diagnosis. According to the Report of the Surgeon General's Workshop on Children with HIV Infection and Their Families, over 75 percent of babies born with AIDS are black or Hispanic. Public health experts predict a substantial increase in pediatric AIDS cases by 1991, ranging from 3,000 cases estimated by the Public Health Service to 10,000 to 20,000 AIDS cases predicted by the National Commission to Prevent Infant Mortality.

CDC categorizes pediatric AIDS cases as children of a parent with or at risk of AIDS, hemophiliacs, or children who became infected through a blood transfusion. For a large majority, epidemiologic data suggests perinatal transmission from a mother who uses intravenous drugs or is the sexual partner of an intravenous drug user. Most pediatric AIDS cases that are being diagnosed now fall within this category, as transmission to hemophiliacs and through blood transfusions have been largely prevented with new blood screening methods.

Hospitals serving pediatric HIV cases, especially urban hospitals in areas with a high incidence of drug abusers, report a growing problem with children with HIV infection who must remain in the hospital when it is no longer medically necessary for them to be there simply because there is no one to care for them at home. In some cases the parents are drug addicts, are themselves ill with HIV infection, or have previously died from HIV-related diseases and the child has been abandoned. In other cases, the family may be homeless, or the parents are ill and there is no extended family able to take care of the child.

As a result, these children must live in a hospital setting, receiving intermittent attention from a variety of attendants, rather than experiencing the stimulation and bonding with a constant care giver that occurs in a home atmosphere. In addition, they unnecessarily occupy costly hospital beds and stretch hospital budgets when a less expensive, community-based setting would better meet their needs.

While hospitals and service agencies are stretched to their limits in some areas with a high incidence of pediatric HIV infection, other areas have yet to face the problem. While a serious problem now, care of an increasing number of HIV-infected children may overwhelm hospital budgets in the future unless a plan is developed to place these children in more appropriate settings, either with their own families or, where that is not possible, in a foster home or small group home.

Obstacles to Progress

The Commission has identified the following obstacles that must be overcome in order to provide proper care for these children:

- Parental drug abuse.
- Medicaid coverage for HIV-infected children which does not extend to home or community-based health care.
- The overburdened and underfinanced foster care system, characterized by a scarcity of foster homes for all children, especially those with HIV infection.
- Lack of collaboration and cooperation at the federal, state, and local levels to provide a continuum of services for these children.

The Commission has heard testimony from individuals and groups who are working to provide homes for infants and children with HIV infection. Although the societal problems giving rise to children boarding in hospitals encompass some of the most difficult issues to resolve, such as drug abuse, unemployment, school drop-outs, teen pregnancy, sexual abuse, prostitution, crime, homelessness, and poverty, the Commission believes that home settings can be found for these children. The first option should be to provide supportive services to nuclear and extended families. In addition, utilizing special training and support services and special foster care rates, foster families should be found for children with HIV infection who cannot return to their biological families.

Because of the scarcity of individual foster homes, group homes must also be developed for HIV-infected children. The Commission has heard testimony about outstanding model homes which are small, humane, and tailored to the needs of small children. Group homes like these should be developed to provide transitional homes while the child is waiting to return to his or her biological family or for an individual foster home to be found. Group homes should also be developed as intermediate care facilities for those children who do not need the services and technology of an acute care hospital, but do need medical services (such as oxygen, catheters, or physical rehabilitation services) which cannot be supplied in custodial foster homes.

Supporting these families and providing foster care will be cost-effective. For example, according to an informal survey by the Child Welfare League of America and the National Association of Children's Hospitals and Related Institutions, the cost of hospital care for these children ranges about $1,200 per day compared with specialized foster care which averages about $100 per day. Providing support services needed to keep families intact and developing foster homes and foster group homes will improve the overall well-being of these children, while reducing the costs of maintaining them in expensive, acute care hospitals.

RECOMMENDATIONS

The Commission has the following recommendations, especially for areas with a high incidence of pediatric HIV infection:

8-60 State and local social service agencies should establish a special HIV unit charged with development of a comprehensive care program for biological and foster families with children with HIV infection. Children with HIV infection should be assigned to case managers who will be responsible for developing networks to provide supportive services, including visiting nurse and other medical services, counseling and mental health services, nutritional programs, day care, and housing.

8-61 State and local social service agencies should train special caseworkers to be assigned to cases involving HIV infection. Case loads should be small so that the caseworker will be readily available to support the family in time of crisis.

8-62 All social service agencies working with HIV-infected children should encourage kinship foster care, which has been a frequent solution in minority families especially. In particular, the grandmothers of children with HIV infection have come forward to care for them and should receive appropriate support services to enable them to provide homes for these children. Through local community and church groups, agencies should develop outreach programs for grandmothers and other relatives of children with HIV infection.

8-63 Social service agencies should undertake aggressive recruitment of foster families, including contacting existing networks of foster parents in the community and employing publicity to focus public attention on these children and the need for foster homes. Agencies should consider non-traditional foster parents, including single and handicapped individuals, older parents, and senior citizens for children with HIV infection.

8-64 Agencies funding foster care should give foster parents of children with HIV infection special incentives such as access to day care and respite care and an increased foster care stipend. Day care centers, with specially trained personnel, should be established to make foster care possible for a larger number of parents. Grandmothers and other relatives of children with HIV infection should be made eligible for foster care stipends.

8-65 The Health Care Financing Administration, in conjunction with state Medicaid agencies, should re-evaluate the eligibility of infants with HIV infection for Medicaid through the Supplemental Security Income and Aid to Families with Dependent Children programs. The release of these children from hospitals should not be delayed simply because of the need for confirmatory testing and diagnosis at 15 months to provide Medicaid eligibility.

8-66 The Health Care Financing Administration (HCFA) should encourage and support state social service agencies and Medicaid agencies to collaborate in applying for and using any available waivers to assure coverage for the full range of in-home and community-based services needed by HIV-infected eligible children. The state and local agencies involved should closely monitor the services provided under these waivers and request new waiver provisions from HCFA if necessary.

8–67 The Department of Health and Human Services should provide adequate funding for demonstration programs providing residential care for babies who are abandoned in hospitals and temporary non-medical care for children with serious illness. Programs should include both foster family care and innovative community-based alternatives to hospitalization along with provision of day care, respite care, and other support services for care givers. Model programs should be developed in conjunction with local public social service and health agencies, religious organizations, child welfare agencies, community service, and voluntary organizations. Dissemination and replication of models should be encouraged. Where appropriate, foster and respite care provided through not-for-profit sectarian and non-sectarian organizations should be supported through federal and state funds.

8–68 The Department of Housing and Urban Development should make available to states and localities matching funds for the construction or renovation of small group homes for HIV-infected children. These funds should be available for facilities for day care and respite care for families of HIV-infected children as well as for group homes.

Section IV. Community-Based Organizations

Community-based organizations (CBOs) are private, non-profit, volunteer-based entities that provide a variety of services to the local community and occasionally to a wider domain, such as the state in which they are located. CBOs are, in every sense of the word, community-based. Their very survival is dependent upon local funding and the credibility they have established in the particular community they serve.

CBOs have led the response to the HIV epidemic in this country. AIDS-oriented CBOs began appearing as early as 1981 in areas of greatest infection, and they now appear throughout the country. The development and response of CBOs is an example of how even the worst of times can bring out the best in people. As stated in previous Commission reports, the work of these organizations, particularly at the beginning of the HIV epidemic, has been outstanding. Organizations in the homosexual community provided the leadership and subsequently developed most of the care delivery models followed by others today. There now exists throughout many areas of the country a network of organizations providing services. Most HIV-oriented CBOs have few paid staff, but rather make use of a large pool of volunteers from a variety of professions within the community. These organizations range in size from extremely small (one or two volunteers) to very sizable (thousands of volunteers) serving thousands of HIV-infected persons.

There has been a major increase in the number of CBOs in the black and Hispanic communities who have either expanded their services to include HIV, formed black or Hispanic specific HIV organizations, or who have formed coalitions with other institutions in their communities to address the epidemic.

CBOs vary greatly in their expertise and can provide a broad range of services such as health education, mental health services, health services, social services, medical assistance, case management, support groups, counseling, testing, food programs, clothing banks, and assistance with legal issues, housing, transportation, and utilities. CBOs have successfully used their credibility with hard-to-reach populations to bring education messages to a broad audience and to conduct research. Sources of funding for CBOs vary greatly. According to a Commission survey, funding in general for HIV-oriented CBOs is largely private. However, other data indicate that CBOs which serve blacks and Hispanics have few private dollars. In fact, only one percent of all foundation funds are awarded to Hispanic organizations. Government funds available for HIV-oriented CBOs have been extremely limited and are often channeled through local health departments. This arrangement can be problematic as local health departments have not had longstanding relationships with CBOs. This is especially true for HIV-oriented CBOs and CBOs in black and Hispanic communities.

Obstacles to Progress

- There is currently minimal funding and no clear funding system that provides funds directly to CBOs for either program development and implementation or technical assistance.
- Frequently, the services CBOs provide are to the indigent or those with little or no money to pay

for services. This adds to the already overwhelming financial burden of the organizations.

- Funding periods for grants are often for only a year at a time. This puts CBOs in a constant search for funding and a tenuous financial situation year to year.
- Individual CBOs have been growing at a phenomenal rate to keep up with the demand for services that the growing epidemic requires. Management capabilities within CBOs are often strained, and individuals with little or no management experience often are promoted rapidly to fill the growing needs.

RECOMMENDATIONS

8–69 Funds should be provided by the Department of Health and Human Services for a national technical assistance program for community-based organizations. Technical assistance should include training in general management practices, fund raising, and program development.

8–70 A clear funding system, with increased funds, which provides money directly to community-based organizations, should be established by the Department of Health and Human Services. The grants should be used to provide a variety of services including counseling, prevention and education programs, assistance with housing, food, clothing, transportation, and securing needed medical and social services. Grant applicants should provide evidence of their ongoing coordination with state and local departments of health.

Section V. The Workplace and HIV Infection

Policies concerning the HIV-infected worker involve critical issues for the United States workplace. The impact of HIV will be felt both in terms of the personal suffering of the HIV-infected individual, especially as an employee becomes too ill to work, as well as the reaction of coworkers and members of the public with whom the individual comes in contact. Education about HIV infection and employment policies for infected workers is imperative to enable employers to minimize disruptions in worker productivity, maintain employee morale, and avoid litigation for noncompliance with worker safety procedures or discrimination against HIV-infected employees.

Some employers in both the public and private sectors have established exemplary HIV-related workplace programs and should be commended for their participation in national, state, and local coalitions which have brought issues related to HIV and HIV disease to the attention of the business community. A few employee unions have also been active in both protecting the rights of employees with HIV infection and protecting the health and safety of workers, especially those in occupations where workers might be exposed directly to the blood of individuals infected with HIV.

Corporate Response to the HIV Epidemic

Notable among corporate leaders responding to the HIV challenge are: a group of San Francisco-based companies which formed a Business Leadership Task Force in 1984; the National Leadership Coalition on AIDS, established in 1987, and now numbering over 100 members from businesses, corporations, labor and voluntary groups, and religious bodies; and the Allstate Insurance Company, which sponsored a 1987 conference on AIDS in the workplace, resulting in the report, "AIDS: Corporate America Responds," a resource for both public and private sector employers preparing to establish HIV policies or guidelines.

The "Ten Principles for the Workplace," developed by the Citizens Commission on AIDS for the New York/New Jersey region, is another helpful guide for those involved in setting up HIV-related policies in the workplace.

Workplace Policy

Several federal agencies have developed policy statements covering the management of HIV-infected personnel in the workplace. Among the first to issue such guidelines was the General Accounting Office (GAO). In December 1986, the Comptroller General established a GAO Task Force to determine how the growing incidence of AIDS could be expected to affect GAO and to identify any policy clarifications or changes needed to respond appropriately to the HIV epidemic. The report of the Task Force was published in December 1987 and includes comprehensive workplace policies which meet four objectives:

- Maintain a safe and healthful work environment for all employees.
- Treat an employee with AIDS fairly and humanely.
- Avoid disruptions to GAO productivity.

- Help managers deal efficiently and sensitively with HIV-related illness in the workplace.

In March 1988, the Office of Personnel Management (OPM) issued comprehensive guidelines which outline employment policies for federal workers who are HIV-infected. The Commission commends OPM for developing these guidelines, which offer a compassionate approach to a delicate human situation and provide excellent advice based on open communication, comprehensive education, and sound legal principles. Employers should refer to these guidelines when developing policies for their employees with HIV.

However, the majority of employers in both the public and private sectors have yet to develop programs or guidelines to address this issue. Small businesses in particular remain unaware, for the most part, of the challenges of HIV, although they may be significantly affected because of the size of their work forces, their small profit margins, and their inability to absorb major increases in health insurance costs for an employee with HIV-related diseases.

Regardless of the size of the business, it is the responsibility of every employer to provide a safe environment for his or her work force. Employers should implement HIV-related policies or guidelines *before* a case occurs to give everyone sufficient time to understand the procedures and to demonstrate management's support for protecting the rights of all their employees.

Obstacles to Progress

- Many employers are reluctant to consider policies regarding HIV-infected workers because the epidemic has not yet affected their work forces. They fear publicity associating their business with HIV infection will cause disruption among their work forces and drive customers away.
- The lack of low-cost information about employment policies for HIV-infected workers has deterred many employers, especially small business owners, from implementing HIV policies and procedures.
- Continued leadership is needed in the private sector to help employers, especially those in small- and medium-sized businesses, who may need assistance developing HIV-related policies.
- For federal workers, each individual federal agency has the authority to determine the extent to which it implements the OPM guidelines. OPM does not have the authority to enforce compliance with these guidelines.

RECOMMENDATIONS

8-71 All public and private employers should ensure that their workplace policies provide HIV-infected employees with the same rights and benefits offered other employees with other illnesses and disabilities. Employers are encouraged to use the Office of Personnel Management guidelines as a reference when planning their HIV policies and programs. (These guidelines appear in the Appendix).

8-72 All federal agencies should serve as a role model for the private sector by immediately adopting and implementing the employment policies for HIV-infected workers described in the Office of Personnel Management guidelines. These guidelines establish a policy for employers of responding to HIV-infected individuals just as employers should with an individual with any other disease or disability (i.e., in a compassionate, humane, and fair manner).

8-73 The President should consider requiring all federal agencies to comply with the Office of Personnel Management guidelines and report annually to him on compliance.

8-74 All employers are encouraged to take active roles in the community response to the HIV epidemic by supporting research, education, health care coalitions, and local HIV support groups.

8-75 Large corporations are encouraged to work with other area businesses to help employers develop appropriate HIV-related policies and to develop, print, and distribute education materials appropriate to the workplace.

8-76 Low-cost or free information about model HIV policies and programs for the workplace should be made more readily available through the support of the private sector, non-profit organizations, business and health coalitions, local Chambers of Commerce, and local, state, and federal governments.

8-77 The Centers for Disease Control's National Clearinghouse on AIDS and the General Service Administration's Consumer Information Center should disseminate exemplary publications on HIV infection in the workplace produced by both the public and private sectors.

Employer-Employee Concerns

The Commission believes that HIV-infected individuals, including those with symptomatic HIV infection, should continue their self-sufficiency through employment as long as possible. Every effort should be made to keep disabled individuals, including those with HIV infection, gainfully employed.

Employers are encouraged to provide the same reasonable accommodations, including alternative work schedules and job modifications for employees with HIV-related problems that are offered employees with other illnesses or disabilities. Because HIV is not transmitted in the type of casual contact that generally takes place in the workplace, there is no justification for fear of transmission of the virus in the vast majority of workplace and public settings. In occupations where there is a risk of exposure to HIV, such as police officers, fire fighters, sanitation workers, and hospital workers, it is the employer's responsibility to provide health and safety protection and training for the workers, as was discussed in the chapter on health care providers.

Some controversy exists about the extent of central nervous system impairment experienced by persons with HIV infection and the impact of such impairment on work performance. This question has been of particular concern to those employing persons in stressful and/or high performance occupations, such as airline pilots.

HIV-related dementia was the subject of a World Health Organization (WHO) meeting earlier this year. A statement released by WHO on March 18, 1988 notes that available scientific evidence does not show that the presence of HIV infection in itself implies a likelihood of impaired occupational performance. It states that HIV testing of employees is not useful in predicting the onset of functional impairment in persons who are otherwise healthy.

The Commission concurs with this conclusion and supports the use of more sophisticated measures for assessing the ability of individuals to work in positions requiring top neurological functioning, regardless of whether the persons are infected with HIV. Based on testimony presented before the Commission, it would be misleading to assume that a positive HIV test is an accurate indicator of the physical or mental skills of the person tested. Likewise, a negative HIV test tells very little about an individual's ability to function in a particular job requiring significant manual and mental dexterity.

The question of possible transmission of secondary infections to coworkers by employees with HIV infection has been raised. HIV-infected individuals are susceptible to infections such as *Pneumocystis carinii*, cytomegalovirus, and *Mycobacterium tuberculosis*. Most of these infections are "opportunistic" and occur only in people with lowered resistance because of immunodeficiencies. Organisms such as *Pneumocystis carinii* are present everywhere and only cause an infection in individuals who are immunodeficient. Organisms such as cytomegalovirus are transmitted through intimate contact with infected body fluids and not by the type of casual contact which generally takes place in the work setting.

Tuberculosis in HIV-infected individuals often occurs in organs other than the lungs and in these cases is less easily transmittable than pulmonary tuberculosis. Pulmonary tuberculosis in an HIV-infected individual is no more infectious than pulmonary tuberculosis in any other person. A common tuberculin skin test is not conclusive if a person's immune response is diminished. Therefore, additional diagnostic measures are required to confirm suspected tuberculosis in an HIV-infected person, even relatively early in the course of the HIV infection. The Commission is concerned that no one be unnecessarily exposed to any tuberculosis or other infectious diseases while the disease is in an infectious stage.

It is for this reason that the Commission strongly supports the reasoning in the *Arline* case relating to employment of an individual with a contagious disease, as described in detail in the discrimination section of this report. In *Arline*, the Supreme Court noted that under Section 504 of the Rehabilitation Act of 1973, such individuals would not be "otherwise qualified" for an employment position if they posed a significant risk of communicating the infectious disease to others in the workplace and reasonable accommodation could not eliminate that risk.

The court in *Arline* delineated guidelines for determining whether an individual with a handicap is "otherwise qualified" for employment in terms of the contagious disease. These guidelines include the examination of medical evidence to determine "a) the nature of the risk (how the disease is transmitted), b) the duration of the risk (how long is the carrier infectious), c) the severity of the risk (what is the potential harm to third parties) and d) the probabilities the disease will be transmitted and will cause varying degrees of harm."

As with other contagious diseases, the Commission believes that this reasoning should be applied to the HIV infection and secondary infections from which the individual is actually suffering when an employer is faced with determining whether or not an employee with HIV infection is "otherwise qualified."

With regard to the personal safety of the HIV-infected worker in some occupations, special precautions may be necessary for certain circumstances, such as overseas travel to areas of poor sanitation or disease outbreak, or where there may be an increased risk of transmission of certain infectious organisms, such as in school situations when there is an outbreak of chicken pox, or in large animal veterinary work. HIV-infected individuals need access to information about the type of situations they should avoid to protect their health.

Obstacles to Progress

- Confusion surrounding methods of transmitting HIV has generated understandable but unwarranted fear among employers, causing unnecessary termination of HIV-infected workers.

- Fear of the effects of HIV-related dementia on work performance has prompted employers to request employee blood testing to determine eligibility for employment.

RECOMMENDATIONS

8–78 Employees with any disease or disability, including HIV infection, should be treated with compassion and understanding and allowed to continue working as long as they are able to perform their job. The "otherwise qualified" standards articulated by *Arline* should be applied and reasonable accommodation should be made for the employee.

8–79 Employers should, where indicated to protect the public safety, provide performance testing and evaluation, including neurological assessment, to detect functional impairment. The Commission does not recommend HIV blood screening for this purpose.

8–80 The Centers for Disease Control should classify the transmission modes of organisms which cause secondary infections in HIV-infected individuals. This information should be written in easy-to-understand terms and made available to employers and the general public through brochures or other appropriate means.

Education and Information About HIV

Fear and misunderstanding about HIV infection has been the underlying cause of much of the anxiety, hostility, and discrimination shown towards HIV-infected individuals in the workplace. Education is one of the most formidable weapons for attacking this fear and ignorance and for maintaining a calm work environment, as well as stopping the spread of HIV. Employers should take the initiative to educate their work force about the transmission and prevention of HIV infection and the laws prohibiting discrimination. In so doing, they will become an important part of the solution by educating the nation with the facts about HIV. In addition, the widespread education of adults creates the necessary foundation for educating youth about this disease.

Obstacles to Progress

- The lack of information about HIV infection has prevented implementation of rational solutions to many HIV-related workplace issues and problems.

- Education programs that are not tailored to the concerns of the employees and which do not reflect the culture of the business environment have little chance of success.

RECOMMENDATIONS

8–81 Employers should take a personal and active role in providing both management and employees with information about HIV and its transmission.

8–82 Employers should work with employee representatives as well as area HIV education and health experts to tailor the HIV information program to the needs of the work force.

Section VI. Religious Institutions and Organizations

The Presidential Commission is well aware that the problems associated with HIV and its transmission must be addressed not only by the medical and scientific communities, but also by every sector of society including churches and other religious institutions. The Commission is sensitive to the complexities of discussing moral values in a pluralistic society and recognizes its limitations in this regard. It does not hesitate to note, however, that religious organizations have done a great deal of effective work in the area of HIV, have contributed from an educational perspective in many important ways, and have encouraged others to approach HIV-infected persons and their families with compassion and understanding.

We are aware that many religious-sponsored health care systems have provided medical assistance, hospital care, and residential facilities to all in need, without discrimination on religious or any other grounds. They have been particularly effective in the care of the indigent. We see the religious institutions carrying out a critical role on a continuing basis, and encourage them all to join with medical, scientific, and educational communities to help the broader community recognize the moral, ethical, and spiritual dimensions of the HIV crisis. We believe that religious organizations can be of special assistance in continuing to emphasize the worth and dignity of every human being in providing care and offering hope to those afflicted. Fully aware of the reality that ours is a diverse society, we believe, nonetheless, that it would do a grave disservice to individuals and their families were no recognition given to moral and spiritual guidance.

Treatment of persons with HIV infection requires attention to the *total care* of the individual as a unique person. All care should therefore be rendered in the context of unconditional human dignity. Compassionate care coupled with clinical research to reduce despair and suffering are not exclusive but intermingled.

Religious institutions have made unique and generous contributions in the area of patient care. Their financial liabilities in this regard are already formidable, particularly when they are supporting the care of the indigent in hospital systems.

The religious community establishes two basic tenets: first, HIV is a treatable illness, early diagnosis and early treatment should be the standard; second, HIV is a preventable illness. We have to look beyond quick fixes that only lead to a false sense of security, and actually lead to a greater spread of the disease.

Religious institutions are a powerful force within society against all forms of substance abuse and sexual promiscuity, the risk behaviors that most continue to spread the epidemic. The Commission endorses their efforts and also urges religious institutions to use their significant social presence to continue the struggle against all forms of discrimination.

RECOMMENDATIONS

8-83 The Department of Health and Human Services should study reimbursement regulations and practices with regard to those voluntary organizations which serve indigent populations to ensure that regulations are not unnecessarily restrictive.

8-84 Convocations of religious and lay leaders of the country should be convened in conjunction with health care providers to develop policy guidelines regarding provision of care and education about high-risk behavior. Increased coordination of effort along these lines could be extremely helpful in bringing to fruition so many of the care and education objectives we all share.

8-85 Religious institutions should address their congregations concerning compassionate treatment of persons with HIV disease and should continue to educate their congregations about scientifically substantiated modes of transmission of HIV. This education should allay unwarranted fears and attempt to put an end to discriminatory practices in their communities.

8-86 Religious educators themselves should be provided with a thorough education about HIV so that they, in turn, can provide accurate and consistent information to the laity.

Section VII. Philanthropy

It has very often been the case in American history that in times of crisis or great social change, groups of individuals in the private sector have mobilized quickly to provide assistance. Individual donors and foundations are relatively flexible, and can often respond more rapidly than large government agencies which are tied to funding cycles and long-range program commitments. Especially in the area of social need, foundation funding has traditionally led government efforts.

The HIV epidemic exemplifies this tradition of private sector response. In the earliest days of emerging awareness of the epidemic, it was philanthropy from foundations and individuals that took the lead in funding much of the education and relief efforts that began in major urban centers. While local, state, and federal governments seemed glacially slow to develop policies to effectively deal with the health crisis, CBOs formed to provide desperately needed services. Start-up funds for these much needed efforts came largely from individual contributions and from private and corporate foundations.

Since 1983, private sector funding has grown from an initial five foundation grants totaling $216,000, to over 130 grants in 1986 totaling an estimated $14 million. It is estimated that grants made in 1987 total $25 million. The first funding ventures began in some of the areas hardest hit by the HIV epidemic. In 1983, municipal foundations in San Francisco and New York City funded groups that provided care-related services for HIV-infected persons and organizations that provided community education. Corporate foundations also funded educational programs and developed guidelines for employees and volunteers engaged in epidemic-related work. Also at this time, the private funding for AIDS research began at a grass roots level and grew into the highly regarded American Foundation for AIDS Research (AmFAR), the only national HIV-related research foundation.

Since November 1986, the Robert Wood Johnson Foundation has awarded grants totaling $22.1 million, funding such projects as a four-year national effort providing comprehensive and coordinated care for persons with AIDS as well as research and technical assistance efforts on the HIV epidemic. Proposals currently under consideration total more than $4 million. The Ford Foundation recently announced a partnership forged from among a number of national foundations and corporations to fund a $4.5 million program of care and education in United States communities and abroad. The American Council of Life Insurance has been very active, and the Metropolitan Life Foundation has taken a leadership role in promoting educational efforts, spending over $5 million for national television HIV education programming on commercial stations in addition to education campaigns and program grants.

This commitment, however, is only a small part of the actual potential for private sector involvement. Private foundations in the United States committed only a small percent of available funds for epidemic-related programs last year. Corporations engage in philanthropy in part to maintain a positive corporate image, and controversy associated with some aspects of the epidemic may have deterred initial response. However, positive steps currently being taken by philanthropies reflect a greater willingness to fund socially complex issues. Philanthropies were also presented with obstacles such as the rapidly changing base of knowledge, uncertainties as to the size of the problem or length of funding commitment, and an inability to respond because applications did not meet existing guidelines. The Robert Wood Johnson Foundation, thus far the leader in foundation funding, rewrote their guidelines for grant awards so that AIDS is a major area included in the foundation's overall mission, and initiated a program of funding HIV prevention and services projects at the community level throughout the United States.

Individual philanthropic events associated with the HIV epidemic represent the efforts of many who worked together to create an event that would both raise money and heighten the public's awareness of the need for support. The many benefit events produced by the arts community, in particular, not only paid tribute to those in that community who had been lost to the epidemic, but also provided a unique opportunity for the general public to see well-known individuals calling for an end to discrimination, highlighting the need for more research, and supporting community-based organizations. The design industry created a unique approach to bringing continuity to many such single events by creating the Design Industries Foundation for AIDS (DIFFA), the first industry-wide foundation that serves as a central depository for proceeds, as well as organizes technical assistance contributions of industry members. On an individual basis, film stars and other well-known media personalities donated their services for public service announcements that carried prevention education messages nationwide. In so doing, they heightened awareness that the epidemic is a universal problem and that help and compassion should be the universal response.

In combination, the philanthropic efforts of many segments of society have contributed to educating the American public about prevention, have provided a better standard of care and care-related services for HIV-infected persons, and have done a great deal to lead government funding into more innovative approaches to care planning and care delivery in non-hospital-based settings. Much needs to be done to bring what has been learned through private sector philanthropy to the awareness of government agencies responsible for care and education so that government programs can be modified when necessary to incorporate the successes created by the private sector.

Obstacles to Progress

- The perceived risks of funding HIV-related projects such as a constantly changing knowledge base, explicit messages needed in education campaigns, high visibility and strong association with controversial messages, and long-term commitment needed for funding, have prevented many private and corporate foundations from becoming involved.
- The slow emergence of highly visible corporate and private foundation support for HIV-related projects and a lack of involvement by recognizable corporate spokespersons has contributed to keeping such philanthropic efforts minimal.
- Corporate, foundation, and individual donor reluctance to be associated with the controversial issues of the HIV epidemic has slowed the progress of private sector participation.
- The epidemic was perceived as affecting only one small segment of the population, a community that was perceived as being well organized, successful, and not needing assistance and one with which it was difficult for the broad base of individual donors to identify.
- Organizations working on HIV-related projects and most in need of funding were not likely to approach large national foundations because so few foundations have funded any HIV-related projects by new, small, community-oriented organizations.
- When philanthropic funding *is* granted, it is usually to larger, more established, "safer" organizations, rather than to small local efforts, whose survival is more in jeopardy.

RECOMMENDATIONS

8-87 The nation's business leadership should convene a highly visible conference, bringing together national corporate and foundation leaders and leaders of regional and community philanthropic organizations. The conference should include organizations such as the National Leadership Coalition, the National Business Council, and others likely to represent broad coordinated leadership. Key government officials should be invited to provide a briefing on the epidemic and rationale for corporate and foundation involvement in all aspects of the epidemic.

8-88 Philanthropies should more actively participate in local community involvement by meeting with local HIV-related organizations to determine needs and share information and resources.

8-89 Corporations should focus grant award efforts on areas most underserved by federal and state funding (e.g., housing and food for the homeless, foster care for HIV-infected children, and provision of services for the homebound person with HIV-related illnesses).

8-90 Both the federal government and the private sector funding organizations should more frequently employ challenge or matching grant programs to encourage a wider participation in funding for epidemic relief and education by a broader base of business, foundation, and individual donors.

8-91 National trade associations and their networks should encourage medium and small businesses, as well as those outside major cities on the East and West Coasts, to become more actively involved in funding programs, and should encourage their membership to support local efforts.

8-92 Recipient agencies should make every effort to become enrolled in employee "matching gift" programs, by which a corporation will contribute to a nonprofit organization an amount equal to the employee's contribution.

8-93 Corporations and foundations should develop ways to provide technical support to newly emerging community-based organizations by loaning middle level managers, accounting services, printing and design services, and other practical contributions that will help the new organizations develop technical expertise and increase funding eligibility.

8-94 Government agencies responsible for designing prevention messages targeted to special populations, such as minorities or adolescents, should utilize the services of well-known personalities in the creative arts, film, and television industries to present those messages through well-known role models.

CHAPTER NINE: LEGAL AND ETHICAL ISSUES

Section I. Discrimination

Throughout our investigation of the spread of HIV in the United States, the Commission has been confronted with the problem of discrimination against individuals with HIV seropositivity and all stages of HIV infection, including AIDS. At virtually every Commission hearing, witnesses have attested to discrimination's occurrence and its serious repercussions for both the individual who experiences it and for this nation's efforts to control the epidemic. Many witnesses have indicated that addressing discrimination is the first critical step in the nation's response to the epidemic.

HIV-related discrimination is impairing this nation's ability to limit the spread of the epidemic. Crucial to this effort are epidemiological studies to track the epidemic as well as the education, testing, and counseling of those who have been exposed to the virus. Public health officials will not be able to gain the confidence and cooperation of infected individuals or those at high risk for infection if such individuals fear that they will be unable to retain their jobs and their housing, and that they will be unable to obtain the medical and support services they need because of discrimination based on a positive HIV antibody test.

As long as discrimination occurs, and no strong national policy with rapid and effective remedies against discrimination is established, individuals who are infected with HIV will be reluctant to come forward for testing, counseling, and care. This fear of potential discrimination will limit the public's willingness to comply with the collection of epidemiological data and other public health strategies, will undermine our efforts to contain the HIV epidemic, and will leave HIV-infected individuals isolated and alone.

On the other hand, the Commission has also received testimony about situations in which HIV-infected individuals have been treated with compassion and understanding by employers, coworkers, fellow students, and members of their local community. From these contrasting experiences, it is clear that the key to an enlightened and compassionate response is education and the planning and development of HIV programs and policies well in advance of the occurrence of the first case of HIV infection. The Commission believes that every employer, school system, and community should start that education and planning process now.

In general, because HIV is blood-borne and sexually transmitted, there is no need to treat those infected with HIV in a manner different from those not infected in such settings as the workplace, housing, and the schools. In the vast majority of workplace and public settings there is virtually no risk of the direct exposure to body fluids which could result in HIV transmission. Detailed Centers for Disease Control (CDC) guidelines have been issued for dealing with HIV infection in those cases which require special handling, such as health care workers and other workers who might be exposed to blood or those schoolchildren who lack control of their body secretions.

Therefore, discrimination against persons with HIV infection in the workplace setting, or in the areas of housing, schools, and public accommodations, is unwarranted because it has no public health basis. Nor is there any basis to discriminate against those who care for or associate with such individuals.

It is illegal to discriminate against persons with AIDS in those local jurisdictions with AIDS-specific anti-discrimination statutes, in those states which include AIDS as a protected handicap under their disability anti-discrimination laws, and in programs which receive federal funds. Section 504 of the Rehabilitation Act of 1973 is the federal anti-discrimination statute which prohibits discrimination against otherwise qualified persons with disabilities (including persons subject to a range of AIDS-related discrimination) in any program or activity receiving federal funds.

Nevertheless, complaints of HIV-related discrimination persist and their number is increasing. For example, HIV-related cases handled by the New York City Commission on Human Rights have risen from three in 1983, to more than 300 in 1986, to almost 600 in 1987. Similarly, the Office of Civil Rights which enforces federal disability discrimination law in programs funded by the Department of Health and Human Services reports a rise in complaints related to HIV infection in the past few years. AIDS advocacy groups and civil rights organizations nationwide also are experiencing an increase in HIV-related discrimination cases.

As a witness at the Commission's hearing on discrimination explained, individuals infected with HIV face two fights: the fight against the virus and the fight against discrimination. Just as the HIV-infected must have society's support in their fight against the virus, these individuals must have society's support in their fight against discrimination and must have assurances that policies will be implemented to prevent discrimination from occurring in the future.

One of the primary causes of discriminatory responses to an individual with HIV infection is fear, based on ignorance or misinformation about the transmission of the virus. We cannot afford to let such ignorance and misinformation persist. Each publicized incidence of discrimination, such as the picketing of a school that has admitted a child with HIV infection, perpetuates this ignorance and sows doubts in the minds of those who hear of it. This undermines current and future HIV education programs as well as rational HIV policies.

Furthermore, each act of discrimination, whether publicized or not, diminishes our society's adherence to the principles of justice and equality. Our leaders at all levels—national, state, and local—should speak out against ignorance and injustice, and make clear to the American people that discrimination against persons with HIV infection will not be tolerated.

Just as our society has taken a definitive stand on discrimination against persons with other handicapping conditions and illnesses—such as cerebral palsy, mental retardation, and cancer—society must take a stand on discrimination against persons with HIV infection. The United States has been an international leader in affirming and promoting the civil rights of persons with disabilities. While much remains to be done, as a nation we can take great pride in the progress we have made in embracing persons with disabilities as a part of the mainstream of society. Persons with HIV infection must be clearly and definitively guaranteed their civil rights and be protected against discrimination just as persons with other disabilities are. Such protection enables the HIV-infected person to become a partner with social institutions in limiting further spread of the infection and supporting effective care-giving systems.

Obstacles to Progress

The Commission has identified the following obstacles to progress in combating discrimination against persons with HIV infection:

- There is not a societal standard or national policy statement clearly and unequivocally stating that discrimination against persons with HIV infection is wrong.
- There is no comprehensive, national legislation clearly prohibiting discrimination against persons with HIV infection as a handicapping condition.
- There is a lack of coordinated leadership from our public and private institutions on the issue of discrimination against persons with HIV infection.
- A patchwork of federal, state, and local laws is both confusing and, ultimately, ineffective in preventing discrimination or providing remedies.
- Enforcement of existing anti-discrimination laws is slow and ineffective.
- Education about transmission of the virus and about the laws banning HIV-related discrimination is insufficient. This results in ignorance, misinformation, acts of discrimination, and, in some persons, an irrational fear of association with those who are HIV-infected.

The Commission believes that removing these obstacles and eliminating HIV-related discrimination will require coordinated action by all Americans—by individuals and organizations at the federal, state, and community levels, and in both the private and public sectors. Strong anti-discrimination laws are needed to establish a standard of behavior and to provide remedies in individual cases. In addition, because discrimination occurs in person-to-person interactions, eradicating it from our society will require programs and policies to educate people in order to change their attitudes. Through a combination of laws and education we can promote this change and create a society in which discrimination against those infected with HIV as well as those with other handicapping conditions is unacceptable. Enactment of strong confidentiality laws should also help to alleviate discrimination. The Commission has the following specific recommendations at the federal, state, and community levels.

RECOMMENDATIONS

The Commission believes that persons with HIV infection should be considered members of the group of persons with disabilities, not as a separate group unto themselves. Persons with HIV infection deserve the same protections as all other persons with disabilities, including those with cancer, cerebral palsy and epilepsy. The Commission rejected the notion of providing anti-discrimination protection only for persons with HIV infection, outside of the context of other disabilities.

For the long term, federal legislation which clearly provides comprehensive anti-discrimination protection for all persons with disabilities, including those with HIV infection, is needed. As a critical first step towards passage and enforcement of such federal legislation, the Commission recommends that the federal government take the following immediate, affirmative steps to articulate a strong national policy against discrimination and thereby lay the groundwork for such legislation:

9-1 The President should issue an executive order banning discrimination on the basis of handicap, with HIV infection included as a handicapping condition. This executive order would reinforce existing Section 504 regulations and clarify that all persons with HIV infection are covered by Section 504. Such an executive order would reaffirm existing federal anti-discrimination law which prohibits discrimination on the basis of handicap and would be a powerful message from the leadership of the nation. One basis for this directive could be the excellent policy guidance on "AIDS in the Workplace" recently issued by the Office of Personnel Management.

9-2 A strong anti-discrimination message, clarifying that HIV infection, like other disabilities, cannot be a basis for discrimination, should be a part of all national HIV education and information materials and activities, including the Centers' for Disease Control National AIDS Information and Education Program. In addition to providing the facts about transmission of the virus, national education efforts should emphasize that HIV-related discrimination is both irrational and illegal. The federal government should provide leadership in asserting that HIV-related discrimination will not be tolerated.

9-3 Special incentives or awards for positive, innovative HIV policies and programs in workplaces and schools should be highlighted and promoted by a high-level federal government office, such as the Office of the Surgeon General.

Section 504 and the "Arline" Decision

The Commission heard from numerous witnesses that the anti-discrimination protections afforded persons with HIV infection under federal and state disability laws represent important first steps toward the enactment of necessary, broader legislation. Section 504 of the Rehabilitation Act of 1973 currently prohibits discrimination against persons with disabilities by entities receiving federal financial assistance. Section 504 states that no "*otherwise qualified* individual with handicaps . . . shall . . . solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service."

On March 3, 1987, the Supreme Court handed down its decision in the case of *School Board of Nassau County v. Arline*, 107 S.Ct. 1123 (1987). In *Arline*, the Court held that a person with a contagious disease (in that case, tuberculosis) could be protected by Section 504 since the individual was covered under the definition of a handicapped individual. The Supreme Court indicated that the basic purpose of Section 504 is "to ensure that handicapped individuals are not denied jobs or other benefits because of the prejudiced attitudes or the ignorance of others." The Court emphasized, however, that having a contagious disease does not automatically ensure that a plaintiff will prevail on his or her Section 504 claim. Rather, the individual with the contagious disease must also meet the criteria for being *otherwise qualified.*

The concept of "otherwise qualified" means that an individual with handicaps must meet the qualification standards of the program or activity from which that individual is seeking benefits or services. In the case of an individual with a contagious disease, the Court in *Arline* noted that such an individual would not be "otherwise qualified" for an employment position if the individual posed a significant risk of communicating the infectious disease to others in the workplace and reasonable accommodation could not eliminate that risk. The court delineated guidelines for determining whether an individual with a handicap is "otherwise qualified" in terms of the contagious disease. These guidelines include the examination of medical evidence to determine "a) the nature of the risk (how the disease is transmitted), b) the duration of the risk (how long is the carrier infectious), c) the severity of the risk (what is the potential harm to third parties) and d) the probabilities the disease will be transmitted and will cause varying degrees of harm." This four-part test was recommended to the Court by the American Medical Association.

In other words, the Court enunciated a two-step approach. First, a determination must be made as to whether the individual is an individual with a handicap. Second, the determination must be made as to whether the individual is "otherwise qualified." Only persons who are both handicapped and "otherwise qualified" are protected by Section 504.

The Court in *Arline* also noted that enforcement of Section 504 would not interfere with the appropriate exercise of authority by public health officials. State public health laws generally provide authority for restrictions of individuals with infectious conditions during periods when they may infect others or from activities which may put others at significant risk. This authority is not hampered by the proper application of the Section 504 standard to contagious diseases.

Thus, under Section 504, as recently interpreted by the Supreme Court in the *Arline* decision, individuals with contagious diseases are covered by the statute's anti-discrimination provisions so long as the individual with the contagious disease does not pose a significant risk of infecting others in the work place. The Commission supports the reasoning in the *Arline* decision and believes that it offers a balanced approach which secures the rights of infected individuals while not jeopardizing the health of those who are not infected.

A recently enacted provision of law (the Harkin-Humphrey amendment to the Civil Rights Restoration Act) was intended to clarify the application of Section 504 in the employment context in terms of persons with contagious diseases. It states that:

> "for the purposes of Sections 503 and 504, as such sections relate to employment, such term does not include an individual who has a currently contagious disease or infection and who, by reason of such disease or infection, would constitute a direct threat to the health or safety of other individuals or who, by reason of the currently contagious disease or infection, is unable to perform the duties of the job."

It appears that this amendment is in concert with the *Arline* decision and codifies the existing standards applicable to Section 504.

The *Arline* decision has been critical in ensuring the continued importance of Section 504 in providing protection against a range of HIV-related discriminatory action. Both preceding and following the Supreme Court's affirmation in *Arline* that Congress intended Section 504 to cover contagious diseases, the lower courts have applied Section 504 to claims of discrimination based on AIDS and HIV infection.

Thus, for example, although the Court in *Arline* did not address the question whether asymptomatic carriers of HIV were covered under Section 504 (because the facts of the *Arline* case did not require the Court to examine that specific question), the lower courts have consistently held that the range of HIV-related impairments, including asymptomatic HIV infection, are covered under Section 504. [See, e.g., *Local 1812, American Federation of Government Employees v. U.S. Department of State*, 662 F.Supp. 50, 54 (D.D.C. 1987); *Ray v. School District of DeSoto County*, 666 F.Supp. 1524 (M.D. Fla. 1987); *District 27 Community School Board v. Board of Education of the City of New York*, 502 N.Y.S. 2d 325, 336 (Sup. 1986)]. Parties in these cases, including the Department of Justice in the case of *1812*, took the position that HIV-infected asymptomatic persons are covered under Section 504. The Commission supports the position that Section 504 coverage applies to persons who are HIV positive yet asymptomatic.

Section 504's prohibition against discrimination extends, however, only to federally funded programs and activities. Thus, large segments of the population in the private sector do not fall within its jurisdiction. There is no existing federal anti-discrimination protection for persons with disabilities facing discrimination in the workplace, housing, or public accommodations which do not receive federal funds.

RECOMMENDATIONS

The Commission believes that federal disability anti-discrimination law should be expanded to cover the private as well as the public sector. Specifically, the Commission recommends:

9–4 Comprehensive federal anti-discrimination legislation which prohibits discrimination against persons with disabilities in the public and private sectors, including employment, housing, public accommodations, and participation in government programs, should be enacted. All persons with symptomatic or asymptomatic HIV infection should be clearly included as persons with disabilities who are covered by the anti-discrimination protections of this legislation.

The National Council on the Handicapped, an independent federal agency comprised of 15 members appointed by the President to make recommendations on public policy issues affecting people with disabilities, included a proposal for a comprehensive federal law of this kind in their January 1988 report to the President. Their proposal, the Americans with Disabilities Act of 1988, was recently introduced in the United States Congress. The Commission believes that this type of comprehensive, disability anti-discrimination legislation should serve as a model for federal legislation in this area.

The Commission does not intend for anti-discrimination legislation to invoke affirmative action for persons with HIV infection. In other words, no one would be required to hire an individual with HIV infection based on that status.

The Commission recognizes that particular attention will need to be paid to the impact of such legislation on small employers, as has been done in other civil rights laws. Any disability anti-discrimination law passed should be consistent with, and not go beyond, the reach of existing civil rights laws for other groups such as minorities and women. In carrying out provisions of the new legislation, all persons with disabilities should have access to the same support services as those covered under other comprehensive federal anti-discrimination laws.

The Commission recognizes that passage of more comprehensive disability discrimination legislation by Congress may take time. Therefore, the Commission believes that it is imperative for the federal government to take immediate steps to inform the public regarding existing federal anti-discrimination law and regarding the remedies which are available for those who experience HIV-related discrimination by entities that receive federal financial assistance. Enforcement of existing law must be strengthened.

In 1986, the Department of Justice issued a memorandum which concluded that although federal disability law prohibits discrimination based on the disabling effects of AIDS, discrimination based on fear of contagion was not covered. The absence of any further statement from the Department of Justice has created confusion and uncertainty about its position, particularly since *Arline* rejected the fear of contagion argument. Specifically, the *Arline* decision stated:

> We do not agree with petitioners that, in defining a handicapped individual under Section 504, the contagious effects of a disease can be meaningfully distinguished from the disease's physical effects on a claimant in a case such as this.

To eliminate uncertainty and clarify the applicability of federal disability law to HIV-related conditions, the Commission recommends:

9–5 The Department of Justice, which has been designated to coordinate the enforcement of disability discrimination law for all federal agencies, should issue a follow-up memorandum expressing support for the *Arline* decision and withdrawing its earlier opinion that fear of contagion is not a basis for Section 504 coverage. In addition, the Department of Justice memorandum should take the lead in endorsing lower court rulings by clarifying that persons who are HIV-infected yet asymptomatic, as well as persons with symptomatic HIV infection, are covered by Section 504.

9-6 The Office of Civil Rights within each agency should develop policy guidelines stating that all HIV-infected persons, including those who are asymptomatic, are subject to the jurisdiction of the Office. The agencies should publicize the availability of the services of their Offices of Civil Rights to those who have experienced HIV-related discrimination and should publish their intent to investigate actively all complaints. The agencies should distribute these policy guidelines to all contractors and grantees.

9-7 All agency Offices of Civil Rights should establish a system of aggressive investigation of violations of Section 504 in HIV infection-related cases, including expedited procedures for review of complaints and regular monitoring of those procedures.

9-8 Supplemental funds should be allocated to all agency Offices of Civil Rights to increase staff and resources for the enforcement of Section 504.

State and Local Government Response

In addition to strong federal anti-discrimination legislation, state and local legislation is needed to provide the local administrative procedures and courts as an alternative to federal litigation for enforcement of the rights of the HIV-infected. Local government officials are able to intervene quickly and utilize ongoing relationships in the community for rapid resolution of discrimination complaints. Rapid resolution is needed as the infected individual may well die in the time interval that a typical case is processed.

RECOMMENDATIONS

For state and local governments, the Commission recommends:

9-9 If not now the case, states should amend their disability laws to prohibit discrimination against persons with disabilities, including persons with HIV infection who are asymptomatic or symptomatic, and persons with AIDS, in public and private settings including employment, housing, public accommodations, and governmental services.

9-10 State-sponsored HIV education campaigns should include anti-discrimination components.

9-11 Arbitration, mediation, and accelerated settlement procedures and programs should be developed and utilized to assist in the speedy resolution of HIV-related discrimination complaints. Mediators and arbitrators should be trained to deal with the special circumstances surrounding HIV-related discrimination cases.

Community Response

One of the primary barriers between those infected with HIV and those not infected is the widespread belief that HIV infection is someone else's problem—there is no need to become educated about it. Individuals in large and small communities across the country are discovering that this is not the case, as they have learned to accommodate individuals with HIV infection living in their midst. In those communities which have developed HIV-related policies and guidelines for health care settings, the workplace, and the schools, and had their programs in place before the first case of HIV infection appeared, fears were reduced and individuals with HIV infection have been accepted. In some cases, where community leaders have not educated the community and not developed policies in advance, the result has been discrimination fueled by fear and ignorance, leading to divisiveness in the community and suffering for the family and friends of the infected individual.

To prevent discrimination, the primary tools at the local level are comprehensive, participatory educational programs, advance planning, and preparation. Educational programs about the transmission of the virus, the laws against discrimination, and the reasons for compliance should be developed by employers, school systems, and health care providers. Education should be provided in simple language for the layman and it should come from a person who has the confidence of those being offered the information. Local officials in government, business, public health, schools, and religious and community organizations should assume a leadership role in this effort.

RECOMMENDATIONS

Specifically, the Commission recommends:

9-12 Organizations representing health professionals should adopt a public policy stating that their members have an ethical obligation to treat patients with HIV infection in a non-discriminatory fashion. These organizations should develop education programs for their members which include education on non-discrimination.

9-13 Religious leaders should take an active role in the anti-discrimination education effort with members of their parish or congregation. In addition, religious institutions should develop outreach programs for individuals in their community with HIV infection and should involve the congregation or parish members in volunteer activities.

9-14 Employers should develop an HIV education program for all employees. Education programs to combat discrimination should emphasize two goals: information about transmission to prevent the further spread of HIV infection and education about legal issues—such as how to ensure confidentiality and prevent discrimination. This approach should be used in all workplace settings.

9-15 Employers should have each department or office review and revise policies and procedures in light of medical and legal information related to HIV infection, and, where applicable, interact with the community to further public education about HIV infection. This last step may be most applicable to the public sector.

HIV and the Schools

The Commission has heard testimony about the experiences, both good and bad, of a number of HIV-infected schoolchildren. Important lessons can be learned from those model communities which have policies in place regarding HIV infection in advance of the first case, and have been able to accept the HIV-infected individual in their schools without fear and discrimination. In some school districts, a well-coordinated system of educational programs has produced an enhanced sense of community pride and satisfaction from having worked together to fashion an enlightened, rational policy on HIV infection for the schools. The Commission has been impressed with the courage and compassion which school and public health officials have displayed in planning and preparing for a positive outcome. A number of common principles emerge from the experiences of these model communities. The recommendations in this section should be implemented in conjunction with the school-based education recommendations in the education chapter of this report.

RECOMMENDATIONS

Specifically, the Commission recommends:

9-16 Each school system should establish a board-developed policy, with accompanying guidelines, for dealing with an individual with HIV infection in the school *before* it is confronted with the first case. The Centers for Disease Control or other public health guidelines should be utilized but the policy should be flexible and allow each case to be dealt with on an individual basis, based on medical facts.

9-17 Educational materials about the transmission of the disease and the anti-discrimination laws should be developed and disseminated and, where necessary, explained fully by legal and medical experts. Age-appropriate materials on these topics should be developed for students.

9-18 School officials should identify a decision-making structure to review all HIV policies and procedures and to deal with each individual case. Legal, medical, and public health consultants from the community should be involved.

9-19 Open public meetings should be scheduled, featuring school officials, medical and legal consultants, and community officials, to discuss the board's policies and the rationale for its decisions. School officials must be prepared to educate the entire community, including parents, public officials, clergy, pediatricians, students, and media representatives, about the reasons for the board's decisions. Support and counseling should be offered to employees, parents, or children who are troubled by the board's decision.

9-20 In any communications about specific HIV-infected individuals, the confidentiality of the schoolchild or staff member should be maintained to minimize the opportunity for discriminatory behavior.

9-21 A team should be formed with responsibility for reviewing all aspects of the case on an ongoing basis and monitoring medical or legal developments that might affect school district decisions.

9-22 School officials should actively participate in community education efforts so that they support acceptance of HIV-infected individuals in the schools in a non-discriminatory manner.

9–23 Educational associations should disseminate information to their members on the policies and procedures used by those communities which have accepted an HIV-infected individual in their schools without fear and discrimination.

HIV and Health Care Settings

The Commission has heard testimony that some hospitals and some health care workers in hospitals have been unwilling to care for HIV-infected persons or have provided inappropriate care because of fear. Steps must be taken to eradicate this fear because these institutions are critical sources of care and are leaders in community attitudes.

Over the next five to 10 years, even more community-based health care facilities, such as group homes, nursing homes, hospices, and mental health facilities, will be needed in many communities to care for patients with HIV infection. Long-range planning for these facilities must be undertaken now in order to avoid fearful and discriminatory reactions from the community.

RECOMMENDATIONS

Specifically, the Commission recommends:

9–24 Hospitals and providers of health care to HIV-infected patients should establish a mandatory education program for all hospital employees, including an antidiscrimination component and professional, confidential counseling for all employees. Health care workers need to be reminded about the social context of HIV infection and the need for confidentiality and protection of private medical information.

9–25 Health care providers dealing with patients with HIV should make available a patient care advocate, if one does not yet exist, to regularly contact individuals with HIV, so that patients could confidentially report treatment problems. Health care professionals who have repeated, substantiated complaints made against them, and who resist education, should be formally reprimanded and placed on probation. In general, the Commission feels that remedies such as this should be short-term in nature and could gradually be phased out.

9–26 State and local governments and health care providers should develop long-range plans now to anticipate the need for community-based health care facilities, and should develop a strategy to educate community members to accept facilities and prevent discriminatory responses.

9–27 Those working to educate a community in preparation for acceptance of patients with HIV infection should develop a strategy to prevent discrimination. Some important points to include are: allowing time for education; knowing the legal issues involved; mobilizing political, community, and religious leaders for support; bringing in legal and public health experts; meeting with people who have concerns and listening to their concerns.

Section II. Confidentiality

Rigorous maintenance of confidentiality is considered critical to the success of the public health endeavor to prevent the transmission and spread of HIV infection. Current public health strategies for fighting the spread of HIV infection are entirely dependent on voluntary cooperation. To encourage individuals to come forward voluntarily for necessary testing, counseling, and treatment, our health care system must be viewed with confidence and trust by those in need of its services. Individuals entering the system must be convinced that information about their health will be kept confidential by those in the system. Aside from the illness itself, it is discrimination that is most feared by the HIV-infected. An effective guarantee of confidentiality is the major bulwark against that fear. A federal statute that carefully balances the need for confidentiality of HIV information against the protection of the public health is a necessary and appropriate response to confidentiality concerns.

To confirm our commitment to the principle of confidentiality in this epidemic and to ensure national uniformity in confidentiality protection policies, it is important for the federal government through legislation to take a leadership role in assuring the confidentiality of HIV-related records, while defining those situations in which information must be shared. In addition, state model confidentiality legislation must be developed and passed as reinforcement to federal confidentiality protection.

The federal government and the states, however, cannot alone carry out a successful strategy for safeguarding against breaches of confidentiality. In addition to legislative initiatives by the government, there must also be a concurrent commitment on the part of the public health and health care communities to reaffirm their time-honored standards for confidentiality and emphasize to all constituents that violations of confidentiality will not be tolerated.

In addition, the role of the individual with HIV infection and his or her family is important in ensuring confidentiality, as their need to communicate with others often leads to indiscreet violations of confidentiality.

Obstacles to Progress

The Commission has identified the following obstacles to progress in confidentiality protection:

- There is considerable variance in the way individual states currently provide for confidentiality of HIV information. This lack of uniformity causes confusion and arbitrary consequences, and bars the establishment of an effective national confidentiality policy.

- There appears to be a lack of confidence that the confidentiality of HIV-related information will be maintained regardless of the law. Many perceive confidentiality protection as lacking, even when adequate safeguards exist. One particular area of concern is the confidentiality of HIV information held by insurance companies.

- Many state confidentiality statutes leave "holes" in substantive areas, such as blood donor HIV information held by hospitals, blood banks, and court disclosures.

- Health care systems have not been inclined to define narrowly "need to know" of identifier-linked information, resulting in a system where safeguards against disclosure are difficult to maintain.

- There is a need for clear and comprehensive policies on the confidentiality of HIV information held by the federal government, including the military.

- Many persons do not understand that it is possible to warn someone about an exposure to HIV without revealing the name or exact identity of the source of the exposure.

RECOMMENDATIONS

In addressing these obstacles to progress in confidentiality protection, the Commission recommends the following:

9-28 Adoption of federal legislation that mandates that identifying information obtained by any provider, laboratory, payor, or agency through HIV testing and counseling cannot be disclosed without the written consent of the individual except under the following circumstances:

- to members of the individual's direct care giving team (i.e., the attending physician, primary or staff nurse, consulting physicians with a special need to know, or outpatient case manager).
- to health care workers accidentally "exposed to the blood or blood contaminated body fluids" of the individual, as defined by the Centers for Disease Control guidelines, where information on exposure cannot otherwise be shared without identifying the individual.
- for statistical reports if used in such a way that no person can be identified.
- to the state health agency, if required by state or federal law or regulation for epidemiologic or partner notification purposes.
- to blood, organ, semen, or breast milk banks that have received or will receive blood, an organ, semen, or breast milk from the individual.
- to a spouse or sexual partner when the individual will not inform such party with respect to the identifying information.
- by a court order issued pursuant to application of a state public health officer. Court proceedings held in connection with disclosure requests by state public health officers should be held in private. Prior to requiring disclosure, the individual should be provided an opportunity to participate in the proceeding to determine whether a disclosure will be ordered. Records of the proceedings should not be open for public inspection and should be sealed at the close of the proceeding. Public health agencies should advocate that court orders for disclosure of name-linked information should not be issued except when compelling reasons for disclosure are demonstrated.
- to the victim of a sexual assault.

The statute should classify violations of confidentiality as misdemeanors, punishable by a fine of up to $10,000.

The statute should not preempt state statutes which are consistent.

The statute should restrict the re-release of information shared except as provided within the entire body of the statute.

9-29 Federal and state information and education efforts should continue to emphasize the importance of confidentiality to the success of HIV prevention strategies.

(9-30) Public health and health care institutions should adopt strict policies regarding administrative or disciplinary action to be taken if a staff member discloses confidential information, and these institutions should regularly provide training on these policies for all employees and volunteers.

Agencies responsible for accrediting or licensing health care institutions should require as part of their accreditation or licensing process that such institutions adopt strict confidentiality policies. Accrediting and licensing agencies should prepare and publish guidelines for confidentiality policies, and, in their periodic reviews of health care institutions, evaluate institutions' confidentiality policies for consistency with the agency's minimum standards of compliance.

(9-31) Educational programs on confidentiality should discuss:

- the special sensitivity that must be accorded information about HIV-infected individuals.
- the adverse consequences that could occur if information is erroneously released.

(9-32) Educational programs for all health care workers should emphasize the importance of confidentiality.

(9-33) Insurance companies should adopt clear and comprehensive policies regarding the confidentiality of HIV-related information in their possession. Special care must be taken to avoid inadvertent conveyance of HIV-related information to a proposed insured's employer (even in those situations where the employer is the applicant) or agent, or improper access of such information through the Medical Information Bureau.

9-34 Clear and comprehensive policies must be adopted by the federal government with regard to the confidentiality of HIV-related information held by institutions of the federal government, including the military.

9-35 Health care-giving institutions must assure patients that confidentiality will be respected, except in the most explicit and rigorously defined instances. Patients should be advised of the potential consequences should they voluntarily disclose confidential HIV information.

Section III. Health Care Provider Notification of Sexual Partners

Adherence to the principle of confidentiality does not relieve our responsibility to protect those who may unknowingly be in immediate danger of being exposed to HIV. A successful approach to the HIV epidemic will need both to recognize the pivotal importance of protecting the confidentiality of HIV-related information and to devise clear programs, policies, and procedures for protecting uninfected persons. The primary ethical obligation to warn rests with the infected individual.

The health care provider should not have a legal duty to warn a patient's sexual partner in these instances, as some court cases have held in other third party warning situations. Notifying sexual partners, as a legal responsibility, is the responsibility of the state or local health department as discussed in Chapter Six. The health care provider's obligation in these instances is to advise the infected individual about behaviors that may cause harm to others, to counsel the patient to notify third parties, to persuade the infected individual to behave in ways that will reduce, if not eliminate, the risk, and to fulfill any legal obligation to notify the state or local health department of cases of HIV seropositivity or the diagnosis of AIDS. Beyond that, a health care provider who concludes that a patient cannot be persuaded to notify a sexual partner at risk should have the option, but not the obligation, to inform the sexual partner.

Federal legislation should be adopted setting forth a uniform policy on third party warnings about HIV outside of the usual public health notification process. At present, there is considerable controversy on the question of a physician's liability for failure to warn third parties and on the application of various state confidentiality statutes to this issue. Very specific federal legislation that permits notification of spouses and sexual partners at risk of contracting HIV would provide needed guidance to health care providers faced with infected patients who refuse to inform such persons of their infection. Consistent with our recommendation that the federal government should clearly delineate where confidentiality may or may not be violated, notification of third parties at risk should be included in confidentiality legislation as an instance when the confidentiality of HIV-related information may be breached.

Inclusion in the more stringent protection of a confidentiality statute will also emphasize that notification of sexual partners is a compromise of the confidentiality of HIV-related information and should, therefore, be exercised only in the narrow, specified circumstances.

Obstacles to Progress

The Commission has identified the following obstacles to progress in notification of sexual partners:

- Difficulty exists in appropriate reconciliation of the rights of partners to notification and codes of medical ethics that have long and appropriately asserted that communications between doctors and patients are privileged and that doctors must maintain the confidentiality of patient communications.
- There is considerable controversy surrounding the legal liability of a physician for failure to warn an endangered third party which is confused with the public health responsibilities in partner notification.
- Many health care providers are not skilled in providing proper counseling.
- Given the demands of clinical practice, it is difficult for health care providers to perform third party warnings in an appropriate manner.

RECOMMENDATIONS

In addressing these obstacles to progress in health care provider notification of sexual partners, the Commission recommends the following:

9-36 Adoption of federal HIV confidentiality legislation that includes a provision permitting, in specific instances, disclosure by health care providers to a patient's spouse or other specific sexual partner at risk of contracting HIV.

9-37 State statutory provisions for health care provider notification of sexual partners concerning risk of HIV infection should be tied to stringent protection of confidentiality.

9-38 Notification provisions must specify those persons who are authorized to do the notification.

9-39 Notification provisions should include sanctions for confidentiality breaches that are inconsistent with the terms of the statute.

9-40 Notification of sexual partners by health care providers should be discretionary and should not be imposed as a legal duty to warn. However, all health care providers should report HIV cases with identification to state public health authorities. Using the information reported by providers, all public health agencies should be involved in partner notification programs as discussed in Chapter Six. In no case is the identifying information to be released by the agency to the person notified or forwarded to other agencies such as the Centers for Disease Control.

9-41 All health care providers and public health officials should counsel patients about behaviors that may cause harm to others, encourage them to notify sexual partners, and teach strategies for prevention of the spread of the virus.

9-42 The health care provider's decision to warn should be made on a case-by-case basis and should consider such factors as:

- the patient's own statements, including commitment to notify third parties;
- the patient's relationship with the third party;
- the potential additional risk presented by a delay in notification;
- whether the third party is pregnant or considering pregnancy;
- the likelihood that the third party has no reason to believe that he/she is at risk;
- the availability of a partner notification program in the local public health department;
- the strength of the physician-patient relationship; and
- other material factors.

9-43 Education programs for health professionals should include basic skills which enable them to become more adept in counseling HIV-infected individuals and their partners, including the ability to explain viral transmission accurately and clearly in nontechnical language. The curriculum should also include principles of psychosocial counseling and techniques for supporting individuals in patient-managed notification. In addition, the curriculum should clarify the procedures for professional-managed notification if the HIV-infected individual does not warn partners within a specific time frame set by the state. To help train these individuals, HIV counseling programs should be incorporated in the following:

- existing professional education process.
- continuing medical or professional education.
- professional societies and associations.
- existing and planned HIV regional education and training centers.

9-44 Counseling of persons notified should include the provision of information on testing, community health care and other support services available to HIV-infected individuals.

9-45 Notified women of childbearing age and their sexual partners should be provided access to counseling about the risks of perinatal transmission.

Section IV. Criminalization of HIV Transmission

Extending criminal liability to those who knowingly engage in behavior which is likely to transmit HIV is consistent with the criminal law's concern with punishing those whose behavior results in harmful acts. Just as other individuals in society are held responsible for their actions outside the criminal law's established parameters of acceptable behavior, HIV-infected individuals who knowingly conduct themselves in ways that pose a significant risk of transmission to others must be held accountable for their actions. Establishing criminal penalties for failure to comply with clearly set standards of conduct can also deter HIV-infected individuals from engaging in high-risk behaviors, thus protecting society against the spread of the disease.

Because of the problems in applying traditional criminal law to HIV transmission, however, states should review their criminal codes to determine the possible need to adopt a criminal statute specific to HIV infection. Use of traditional crimes such as murder or attempted murder to prosecute an individual for HIV transmission presents such difficulties as proving that the intent of the HIV-infected individual was to transmit the virus and to cause the victim's death, and proving that the act of transmission was the actual cause of death. Although the assault model provides a more useful tool for criminal prosecution of HIV transmission, the penalties for assault would prove too lenient in those cases where the transmission was intentional. An HIV-specific statute, on the other hand, would provide clear notice of socially unacceptable standards of behavior specific to the HIV epidemic and tailor punishment to the specific crime of HIV transmission. Indeed, a few states, including Florida, Idaho, Louisiana, and Nevada, have recognized the advantages of legislation specific to HIV transmission and have passed criminal statutes ranging from prohibiting a person infected with HIV from having sexual intercourse without informing sexual partners of the infection to prohibiting HIV carriers from donating blood. While we encourage continued state efforts to explore the use of the criminal law in the face of this epidemic, we caution that criminal sanctions for HIV transmission must be carefully drawn, must be directed only towards behavior which is scientifically established as a mode of transmission, and should be employed only when all other public health and civil actions fail to produce responsible behavior. The use of criminal sanctions should not substitute for use of public health measures to prevent transmission, as discussed in Chapter Six.

Obstacles to Progress

The Commission has identified the following obstacles to progress in criminalizing the transmission of HIV:

- Traditional criminal laws are not well suited to the prosecution of HIV transmission.
- Penalties for prostitution are too lenient and enforcement of prostitution laws is erratic.
- Concern that criminal sanctions will undermine public health goals by diverting attention and resources from effective prevention policies such as education, testing, counseling, and partner notification and inhibit people from seeking testing.
- The view of some that criminal sanctions are primarily punitive rather than preventive and as such would not effectively deter HIV-infected individuals from engaging in behaviors likely to transmit the virus.
- Fear of intrusive policing of private sexual activity and danger of selective prosecution and misuse of the criminal law to harass unpopular groups.

RECOMMENDATIONS

In addressing these obstacles to progress in criminalizing the transmission of HIV, the Commission recommends the following:

9-46 Adoption by the states of a criminal statute—directed to those HIV-infected individuals who know of their status and engage in behaviors which they know are, according to scientific research, likely to result in transmission of HIV—clearly setting forth those specific behaviors subject to criminal sanctions. With regard to sexual transmission, the statute should impose on HIV-infected individuals who know of their status specific affirmative duties to disclose their condition to sexual partners, to obtain their partners' knowing consent, and to use precautions, punishing only for failure to comply with these affirmative duties.

9-47 HIV criminal statutes should include strong, uniform confidentiality protection.

9-48 Prior to instituting a case against an accused individual, prosecuting officials should consult with local public health officials to determine whether to prosecute the individual for an HIV transmission criminal offense or whether public health intervention would be more appropriate. Systems should be set up to facilitate this dialogue.

During the presentation of the state's case, the prosecuting attorney should introduce, consistent with federal and state rules of evidence, any information held by the public health department regarding intervention measures taken with respect to the infected individual.

9-49 HIV criminal statutes should include a provision stating that prior to termination of any period of incarceration or probation under the statute, the offender will be interviewed by state public health officials for the purpose of determining whether further action will be required by the public health authorities upon release of the individual. Such interview proceeding must be subject to procedural due process safeguards, and any action taken by the public health authorities must be pursuant to powers provided by the state's public health laws.

9-50 States should refrain from criminally prosecuting HIV-infected individuals for HIV transmission when the alleged criminal conduct did not involve a scientifically established mode of transmission.

9-51 Prostitution laws should be strictly enforced.

Section V. Sexual Assault and HIV Transmission

The HIV epidemic has added a new and disturbing specter to the problems of sexual assault victims. Witnesses have testified before the Commission about the increase in the numbers of victims of sexual assaults and their growing concern over the possibility of exposure to the HIV virus as a result.

Victims of sexual assault deserve consideration and must be given attention and support so that they will not be forgotten in the tragedy surrounding the HIV epidemic. The Commission believes that it is important to plan an approach which will take into consideration both the emotional impact of an assault and the possible exposure to HIV. This approach must balance the rights of the victims to be treated with fairness and dignity with the due process rights of the perpetrators.

In 1985, the FBI recorded 87,340 rapes in the United States, or approximately 239 rapes per day. This number greatly underestimates the true scope of rape since it includes only female victims 16 years and older and only instances that were reported to police. Government estimates suggest that for every rape reported to police, three to 10 rapes are not reported, making rape one of the most underreported crimes. In addition, the American Humane Association estimates that 110,878 children were reported as victims of sexual maltreatment in 1984, a 54 percent increase from 1983.

The risk level for HIV transmission to sexual assault victims is as yet unestablished. However, the physical trauma associated with sexual assault increases the vulnerability of body tissue and must be factored into assessments of risk of viral transmission. In addition, the high-risk behavior of many sexual offenders (the term sexual offender refers to the perpetrator of a sexual assault), in turn, increases the risk level of their victims. Children who are sexually molested are potentially at elevated risk of infection if the sexual offender is HIV-infected, since many cases involving children have patterns of repeated contacts over long periods of time. The Surgeon General has stated that all child sexual assault victims must be considered at risk for exposure to HIV.

Studies of sexual offenders and child molesters indicate that many often have large numbers of victims and high rates of recidivism. Therefore, even a small number of infected sexual offenders have the potential for infecting large numbers of people.

Victims or their immediate family members are aware of their risk of exposure to sexually transmitted diseases, including HIV, and are beginning to ask questions about, and exhibit anxiety over, possible exposure to HIV. Many are requesting to be tested. Even in cases where the sexual offender is apprehended, the issues of testing perpetrators who refuse to be tested voluntarily without their consent and state laws governing confidentiality of all HIV test results may obstruct the victim's ability to get information on HIV status. This restriction on access to information can cause the victim anxiety added to the trauma of the crime itself. If HIV status information is available, it should be provided to the victim in the context of a support and counseling system which can help the victim understand the information and make decisions about testing or personal conduct.

The complexity of establishing HIV exposure and subsequent seroconversion requires follow-up over time. The presence of antibodies may take weeks or months to determine, and follow-up of sexual assault victims will be necessary. Unfortunately, success of past programs which included follow-up counseling have not been impressive for a variety of reasons.

Obstacles to Progress

The Commission has identified the following obstacles to assisting victims of sexual assault crimes in light of possible exposure to HIV:

- HIV testing is not currently included in the routine tests for sexually transmitted diseases offered to sexual assault victims. Where testing is requested, it may be expensive. Since routine tests are usually performed as soon as the assault is known, an HIV antibody test of the victim would not reveal exposure as a consequence of the rape.

- There are no published studies available on the incidence of HIV infection as a result of sexual assault or among perpetrators.

- The criminal justice system and most state laws have not addressed fully how to approach the HIV-infected sexual offender.

- Mandatory testing of accused sexual offenders is not widely available.

- In some states, laws prohibit release of information on a sexual offender's HIV status to victims.

- There is no mechanism for reporting cases of HIV-infected sexual offenders once apprehended and subsequent notification of victims.

- Most current counseling programs for victims of violent crimes do not include a component on HIV, and counselors are not currently trained to provide such services.

- Children typically experience problems in coming forward and making adults believe their accounts of molestation.

RECOMMENDATIONS

Monitoring and Data Collection

9–52 Public health officials, criminal justice systems, and various organizations that deal with victims and perpetrators of sexual abuse must collect and compile data so that the scope of HIV prevalence and transmission associated with sexual assault can be determined.

9–53 The Centers for Disease Control should monitor and publish the number of reported cases where HIV transmission occurs through sexual assault including geographic breakdowns.

9–54 Criminal justice and victim service organizations should collect data on the frequency of sexual assault victims' requests for HIV testing and the frequency of positive results for both victims and perpetrators.

9–55 Support for incidence and prevalence studies of HIV among the sexual assault population, such as those currently funded by the National Institute of Mental Health, should continue with increased funding.

Testing and Counseling

9–56 Programs which provide medical and counseling services to sexual assault victims should make voluntary HIV testing a part of the sexually transmitted disease screening process free of charge and make appropriate counseling about assaults and HIV available by trained staff.

9-57 Training programs for HIV blood test counseling and partner notification techniques should include components focusing on the sexual assault population.

9-58 Federal and state public health authorities should provide service providers and counselors who assist child and adult victims of sexual crime with the most current information and training on HIV, along with information on the location of confidential and anonymous testing sites and funding and training for the performance of tests.

9-59 Model programs for the long-term follow-up care of victims who do and do not test positive initially should be developed and funded. If a victim converts to positive infection status, there should be counseling and health care intervention provided throughout the various stages of HIV infection. These individuals should receive highest priority for participation in clinical drug trials.

9-60 Social services, law enforcement, mental health, medicine and community-based services should cooperate to provide effective response to child sexual abuse by a well-coordinated, multidisciplinary team which protects and treats victims and their families and deals effectively with perpetrators, incorporating concerns related to HIV exposure.

9-61 Basic curricula/training programs for health, counseling, and criminal justice professionals should include identification of undisclosed sexual trauma, dynamics of victimization, and patterns of trauma and recovery as well as HIV transmission.

9-62 Victim advocacy programs should increase public awareness concerning the potential impact of HIV on victims of crime through education.

Testing of Offenders and the Victims' Access to Results

9-63 Criminal justice authorities, under the guidance of public health officials, should develop a mechanism to order that a sexual offender submit to an HIV test at the earliest possible juncture in the criminal justice process. The results of such a test should remain confidential and be disclosed only to the victims, if they so desire, and public health officials. Where the victim of the sexual assault is a minor, the test results should be disclosed to the minor's parents and/or caretakers.

9-64 The criminal justice system should periodically conduct follow-up testing of convicted offenders who test HIV negative to monitor for possible development of antibodies or other evidence of infection at a later time, with notification of victims as appropriate.

9-65 In the cases where a sexual offender is not apprehended, or where apprehended and there is a possibility of HIV infection even though current test results are negative, victims should at least be offered testing over time and counseling as to the potential for transmitting the disease and as to proper precautions.

9-66 Adult victims who choose not to know of the sexual offender's HIV status should be informed of the possibility of infection and offered testing and counseling so that they can take appropriate precautions.

Criminal Justice System Approaches to Sexual Offenders

9-67 Courts should utilize restitution orders whenever possible so that sexual offenders are held directly accountable for the financial effects of their crimes.

9-68 State laws and federal laws (in the limited areas where federal laws preside over criminal actions, such as on Indian reservations) should include provisions for enhanced sentencing in cases where sexual offenders commit sexual crimes knowing they are HIV-infected.

9-69 Criminal justice facilities should test all convicted sexual offenders for HIV prior to a parole hearing or release from prison. If parole is granted, a positive test result should affect the degree of supervision the sexual offender receives following release.

9-70 If a convicted sexual offender is HIV-infected, this information should be included in the sexual offender's criminal record and used in sentencing hearings for subsequent sexual assault convictions as a basis to further enhance sentencing. The criminal justice system should restrict availability of information on HIV status to those individuals within the criminal justice system with a need to know. Under no circumstances should this information be released as general public information.

9-71 The criminal justice system should develop and implement sound treatment programs for sexual offenders which include an HIV prevention component.

Section VI. Correctional Facilities

A recent joint study sponsored by the National Institute of Justice (NIJ) reports that as of October 1, 1987, there had been a cumulative total of 1,964 confirmed AIDS cases in 70 federal, state, and local correctional systems responding to the study. This figure represents a 156 percent increase in AIDS cases in all responding United States correctional systems in the two years since NIJ's first survey, and a 59 percent increase in the one year since the second survey in 1986. While most correctional systems have adopted policies in response to the growing problem of AIDS cases in prisons and jails, many key policy issues, such as HIV antibody testing and housing of infected inmates, remain matters of considerable controversy.

New York State corrections officials testified that all prisoners are tested for sexually transmitted diseases (STDs), but that such tests do not include HIV tests. Further testimony indicated that STD-free prisoners are allowed conjugal visits in New York, but that officials did not know whether HIV-infected inmates were allowed conjugal visits because no tests were performed.

Obstacles to Progress

The Commission has identified the following obstacles to progress in the correctional facilities area:

- Many inmate populations contain a high concentration of individuals at risk for HIV infection but few jurisdictions are attempting to assess the prevalence of HIV infections in prison or to intervene in the epidemic by test-linked counseling of at-risk prisoners and subsequent partner notification.
- Many correctional systems are overcrowded.
- The high cost of medical care for HIV-infected inmates is a difficult burden for correctional systems with limited budgets.
- Misinformation is common among inmates and correctional system staff regarding modes of HIV transmission.
- Screening inmates through HIV antibody testing raises many legal and fiscal concerns that have not been addressed in most jurisdictions.
- Policymakers in most states have yet to define the responsibility of the correctional system to protect the community, correctional staff, and uninfected inmates from HIV infection.
- There are concerns about confidentiality and the safety of inmates identified as HIV-infected.
- There are concerns about discrimination against and rights regularly accorded prisoners (e.g., parole and furlough) being denied on the basis of HIV antibody status.
- The lack of HIV tests prior to conjugal visits puts those visiting unnecessarily at risk.

RECOMMENDATIONS

In addressing these obstacles to progress, the Commission recommends the following:

Prevention

Education and training of inmates and staff are a key strategy for curbing the spread of HIV infection in prisons and jails. Education and training programs are important not only as a means of protecting people from infection, but also as a means to counteract misinformation and rumors about HIV, thereby dispelling unwarranted fears about the disease, an especially important goal in the often highly-charged close living quarters of a prison.

9-72 All correctional systems should immediately institute an HIV prevention program for both inmates and staff. These systems should: provide education and training on a regular basis; be based on the most current medical knowledge; include the latest information on risk reduction behavior and technology; and allow for participant involvement such as question and answer sessions, peer education, and counseling. Teams conducting training should include health personnel whenever possible. Training and informational materials should be brief, presented in a clear straightforward manner, and be structured for the educational level and concerns of the particular audience.

Testing

As of November 1987, twelve state correctional systems (Alabama, Colorado, Idaho, Iowa, Missouri, Nebraska, Nevada, New Hampshire, Oklahoma, South Dakota, Utah, and West Virginia) have implemented or are planning to implement mass screening programs. The Federal Bureau of Prisons (FBP) reassessed its earlier policy of mass screening and now tests inmates: prior to release; who exhibit clinical indications of the virus; who request to be tested; who are released for community activity purposes; and who have exhibited predatory and promiscuous behavior. In addition, for study purposes, FBP tests a 10 percent sampling of incoming inmates who are retested at three, six, 12, and 18 month intervals.

9–73 All correctional systems should regularly offer and strongly urge voluntary HIV testing and counseling for HIV infection at intake, at medical check-ups, during incarceration, and before release to all inmates. Counseling and testing should also be regularly offered to staff.

9–74 All correctional systems should adopt HIV testing policies that are consistent with the Federal Bureau of Prisons' policy for testing inmates for HIV. HIV testing programs should also provide for mandatory testing of inmates whose convictions were a result of sex or drug-related crimes or who have a history of intravenous drug abuse. Testing policies should be consistent with applicable state or federal law.

9–75 HIV testing programs instituted by correctional systems should include extensive counseling services pre- and post-testing and while test results are being determined. Counseling of those inmates found to be HIV-infected must be consistent with that recommended for all infected persons, including full information about methods of preventing further spread of infection.

9–76 Rights regularly accorded to all inmates (e.g., parole and furlough) should not be abridged solely on the basis of HIV infection.

9–77 Disclosure of test results should be strictly limited. The correctional system's disclosure policy should specify clearly who is permitted to receive the information, what information is to be released, and under what circumstances. Test results should be reported to public health authorities so that partner notification can be performed.

9–78 The Centers for Disease Control should work with federal, state, and local corrections health officials to evaluate the various inmate testing programs and make those results regularly available to appropriate policymakers.

Housing

The Centers for Disease Control guidelines suggest that no special housing arrangements be made for HIV-infected individuals except under defined medical circumstances. Given the fact that sexual activity and drug use do take place in prisons, segregation may appeal to some prison officials as a means of further limiting the spread of HIV. However, as an infection control device, such "identify and isolate" plans are never 100 percent successful.

9–79 The National Institute of Justice should continue to review and evaluate prison housing policies making up-to-date information and guidance available to prison systems regularly.

9–80 Each correctional facility should establish a policy on how to manage the housing of known HIV-infected prisoners based on such factors as: current public health guidelines, physical space limitations, staffing levels, and prevalence of infection in the facility.

9–81 Correctional facilities should provide a means for protecting those HIV-infected inmates whose safety would be at risk if placed in the general prison population.

Treatment

9–82 The care and treatment available to HIV-infected inmates in correctional facilities should be equal to that available to HIV-infected individuals in the general community.

9–83 Correctional systems should establish drug treatment programs based on the therapeutic community model for those inmates identified as drug abusers and/or incarcerated for drug-related crimes. This model has successfully utilized former addicts as counselors because of their value as role models. The inmate should remain in drug treatment for no less than nine to 12 months unless precluded by the length of the sentence and should be referred upon release to drug treatment facilities near their homes.

9–84 Correctional systems should make counseling services available to all HIV-infected inmates. For successful treatment of inmates who are intravenous drug abusers, counseling is particularly important during those periods immediately prior to and immediately after release. The inmate should receive concentrated counseling on the importance of avoiding risk behaviors and drugs during the pre- and post-release periods. This counseling should also include admonishment that failure to do so could result in immediate disciplinary action as well as affect parole and/or enhance future sentencing.

9-85 Correctional systems should encourage the development of support groups within their institutions.

Section VII. Ethical Issues

Ethical questions present some of the most vexing problems associated with HIV infection and society's efforts to understand it, prevent it, control it, and treat it. Ethics is a discipline which helps us determine what is right and wrong and to act accordingly. Ethical principles such as beneficence, autonomy, and justice guide us in searching for solutions, as do ethical and legal precedents. But the HIV epidemic seems to raise some new ethical questions, or, perhaps more accurately, has produced a new dimension to familiar ethical questions. A number of complex questions are forcing us to define our commitment to principles of compassion, individual liberty, and the public good. Determining the ethically appropriate and feasible response and putting that response into motion is posing formidable challenges for our society.

We recognize that ethical considerations and decision-making are contained in every facet of our discussion of and response to this epidemic. We have chosen to incorporate ethical considerations into all sections of this report. In the preceding sections on discrimination and confidentiality, as well as in the sections on patient care and societal issues, references are made to ethical principles and decision-making, and our recommendations were made in light of those ethical considerations.

In this section the Commission has separated out a few areas for emphasis. These include: the obligations of health care providers; the ethics of treatment decisions; the ethics of research; and, very importantly and too often neglected in the ethical debate, the ethics of HIV-infected individuals, themselves, as well as the ethics of others toward them. There are many excellent discussions of ethical issues surrounding HIV infection in research literature. In this report, considerations of ethical issues are limited to those which surfaced repeatedly during the hearings and site visits conducted by the Commission.

The Obligations of Health Care Providers

History is replete with examples of health care workers providing care and demonstrating a devotion to patients which transcended any possible danger to themselves of contracting patients' diseases. Health care workers have worked valiantly caring for the sick or injured in conditions of squalor, poor sanitation, and exposure to infectious diseases -- as in the cases of cholera, influenza, and the bubonic plague. Some health care workers have suffered, and some have died, as a consequence.

The current generation of health care workers had not confronted an infectious disease that posed such a serious threat. In recent years, most patients requiring care were those with chronic diseases presumably caused by environmental or lifestyle factors, not by microorganisms. But now there is HIV infection, which poses the danger of infection with a blood-borne virus. Health care workers, by virtue of their exposure to blood and body fluids, are at some risk of acquiring an HIV infection while caring for infected patients. In many areas, despite the low risk, health care workers, including physicians, nurses, emergency medical technicians, and others, have been plagued with a fear of this disease that sometimes interferes with their ability and/or willingness to care for infected persons.

In addition to the actual risk -- and the perceived risk -- of infection, some health care workers have expressed disapproval of the lifestyles and behaviors of some of the people who have acquired HIV infection (homosexual men, intravenous drug users, and prostitutes). Some have allowed this disapproval, and a feeling that "they got what they deserved," to interfere with the care they provide to infected persons. Fortunately, this is a minority view, and there are large numbers of health care workers who tirelessly provide quality care to HIV-infected persons in a compassionate and sensitive manner.

The ethical principle of beneficence (do no harm and promote good), amplified by the role of promoter of health and provider of care to which the health professional is committed and licensed to practice, serves as a solid rationale for the provision of care to all who need it. Health care providers also have an obligation to plan for and provide optimal treatment and care to every patient. This necessitates knowledge of and employment of all available technologies to achieve early diagnosis and treatment.

In addition, codes of ethics and statements from the various professional associations provide guidance for health professionals. The Commission applauds these groups for clear statements of obligation. A few examples:

> "A physician may not ethically refuse to treat a patient whose condition is within the physician's current realm of competence solely because the patient is infected with HIV." *—American Medical Association*

> "The nurse provides services with respect for human dignity and the uniqueness of the client, unrestricted by considerations of social or economic status, personal attributes, or the nature of the health problem." *—American Nurses' Association*

Health care providers also have the obligation to protect their patients by maintaining confidentiality of information.

Obstacles to Progress

The Commission has identified the following obstacles to fulfillment of the obligation of health care providers to provide care, in consonance with ethical principles, to HIV-infected patients:

- Although the risk of acquiring an HIV infection from caring for a patient is calculated to be less than one percent (i.e., less than one percent of all possible exposures actually results in transmission of the virus), the perceived risk is great, causing fear and concern about "catching AIDS from patients" on the part of some health care workers and, in the process, forming a barrier to meeting ethical obligations.

- There is an apparent lack of education and awareness on the part of too many health care workers about what the risks are and how to protect themselves. Until this is remedied, they will unwittingly continue to contribute to the nation's misunderstanding of the epidemic.

- Health care professionals face increasingly difficult ethical decisions involving patient care. Technological advances are out-stripping current ethical guidelines, and the study of ethics is frequently lacking in the curricula of health care professional schools.

- Although the professional associations have all issued statements and ethical guidelines, these are just guidelines and not rules. Despite the guidelines, a number of health care workers still refuse to care for HIV-infected persons.

- There is insufficient data on possible variations of risk in different settings (e.g., emergency room) or with different activities (e.g., various invasive procedures), as well as insufficient data on the protectiveness of infection control apparatus.

- Concern about HIV infection may be deterring young men and women from entering the health care professions or certain subspecialties. This may exacerbate an existing shortage in some professions.

- Some providers are concerned that treatment of HIV-infected persons will drive away other patients and place the provider at economic risk.

- Reluctance to be perceived as "overreacting" to the epidemic may be leading some physicians to refrain from regularly offering HIV testing by which they could enhance their ability to diagnose and deliver more informed care.

RECOMMENDATIONS

In response to these obstacles to progress, the Commission makes the following recommendations:

9-86 Health care providers have an obligation to provide care, within the limits of their competencies, to all persons who need it, regardless of their HIV status. This obligation does not preclude appropriate referrals when the provider lacks the technical or professional skills to provide the indicated services.

9-87 Health professional associations should establish or reaffirm clear guidelines on their members' obligations and responsibilities and disseminate them widely to all members. The development of such guidelines should be done with the input and participation of practicing members.

9-88 Health care providers have the obligation and responsibility to become -- and remain -- educated about HIV infection and related subjects so that they can provide competent care to patients and prevent unnecessary risk to themselves.

9-89 Health care providers should employ appropriate infection control procedures at all times. Employers of health care providers have the obligation to assure that necessary equipment and supplies are available and that all workers are adequately trained in their use.

9-90 Health care providers involved in providing direct care to patients have a right to know all known relevant patient information which might assist them in making treatment or care decisions. All health care providers have the responsibility to use this information appropriately and maintain the confidentiality of this information.

9–91 The health professional associations should continue and expand their efforts to educate their members and the public about HIV infection and should include discussions of pertinent ethical concerns.

9–92 The National Institutes of Health should encourage interdisciplinary research efforts in ethics directed toward a better understanding of the processes, elements and components of the ethics of the decision-making process with particular emphasis directed toward the ethical dilemmas raised by the HIV epidemic.

9–93 Health care professionals have the responsibility to educate adequately all patients about the transmission of HIV, including those patients who need assurance that they cannot become infected by going to the same provider or the same health care setting as infected patients. Professional organizations should stress this educational responsibility in all of their education and training curricula on an accelerated basis.

9–94 Physicians have the responsibility to take all feasible steps to achieve accurate, early diagnosis.

The Ethics of Treatment Decisions

The decisions of health care providers about treatment for HIV-infected persons should be based on the same ethical principles as decisions about treatment for an individual with any illness. This includes the presentation to the patient of viable medical options based on scientific data about efficacy and a respect for the patient's right to participate in decisions about his or her own care. Ethically, decisions about individual diagnosis, treatment and care should not be made on the basis of socioeconomic concerns, such as ability to pay, or more global concerns, such as allocation of scarce health care resources. In addition, social prejudices of any type should not in any way influence decisions on treatment.

Obstacles to Progress

The Commission has identified the following obstacles to progress in making ethical decisions about treatment:

- Preferences in treatment are sometimes difficult to elicit from individuals or groups of individuals who have limited education.

- Care givers often lack information, or are discouraged, about medically viable options for HIV infection and its consequences.

- Care givers may be reluctant to discuss future treatment options with patients because of fear, inexperience, or concern about patients' reactions.

- The competence of an HIV-infected individual, especially in the late stages of the disease, may be compromised by neuropsychiatric complications.

- If given the choice, a proportion of those with HIV infection may select a person other than next-of-kin to make critical decisions for them in the event of their incompetence.

RECOMMENDATIONS

9–95 All care givers should give HIV-infected patients the same respect, dignity, and decision-making autonomy as any other patient.

9–96 All health care providers should make informed consent by the patient an essential first step in any HIV-related treatment or intervention.

9–97 All health care providers should give HIV-infected patients the opportunity to express preferences about care and about life-sustaining therapies as early and as often as possible after diagnosis. Legal, psychological, and moral counsel should be made available to all patients to help them express their wishes.

9–98 The nation's universities and health care professional schools, through research grants and study groups, should fund and conduct the further examination of actual and potential ethical controversies which arise in providing care to HIV-infected patients.

Ethical Considerations of Research

In the Commission's limited examination of ethical issues related to research, several areas of concern were brought to the forefront. Of particular concern are: equitable and fair access to clinical trials and experimental drugs; the vital importance and difficulties with informed consent for research protocols; the appropriateness of placebo-controlled trials at certain stages of HIV-related disease; the protection of confidentiality of research subjects; and ethical questions about the allocation of economic and human resources for research. All of these issues are considered in the chapter on research in this report.

Other research issues with ethical underpinnings include the importance of research on education and behavior change, which is addressed in the chapter on education, and the importance of research to help delineate the most effective (from considerations of both therapy and cost) health care services for HIV-infected persons, which is addressed in the chapter on patient care.

In this section on research ethics, we have chosen to limit our discussion to one issue -- ethical considerations relevant to releasing scientific information. Research and scientific investigation about HIV is occurring at a remarkable pace. While this information must be made available as soon as possible to those who need it, it also must be reliable and be presented in an appropriate manner to the general public. The Commission has seen and heard many examples of information released to the public without adequate scientific and peer review, which only contributes to fear, anxiety, and mistrust of scientific information among members of the public.

Obstacles to Progress

The Commission has identified the following obstacles to progress regarding the release of information:

- The timely release of reliable information about all aspects of HIV infection is imperative. Because of this, some scientists and journalists may have overlooked an ethical responsibility to report scientific information after adequate peer review and within an appropriate context for understanding.
- While some journals and organizations have facilitated the dissemination of HIV-related information, the usual review protocols are slow and are seen by some as an obstacle to be bypassed.

RECOMMENDATION

9-99 Scientists and researchers are encouraged to subject all information related to the HIV epidemic to adequate peer review and to report it to the media within a context which promotes understanding among all members of the public, and which minimizes sensationalism.

Ethical Behavior of HIV-Infected Individuals

One of the most basic of ethical principles is that of non-maleficence. Non-maleficence essentially directs us to do no harm. Our society values highly the rights of individuals to privacy and liberty. But liberty entails a responsibility not to harm or interfere with others, a responsibility to be non-maleficent. In this context, the Commission believes that HIV-infected persons have certain ethical responsibilities which they must meet in order to prevent harm to others. Fulfilling these responsibilities is also an affirmation of the rights of others.

Obstacle to Progress

- Persons who are infected with HIV or at risk for infection with HIV may not be aware of, or in some cases not comply with, their ethical responsibility to avoid harm to others.

RECOMMENDATIONS

9-100 Persons infected with HIV or at risk of infection with HIV should take appropriate steps to avoid infecting others. This includes: not donating blood, sperm, or organs; not infecting others sexually; not sharing needles or other sharp instruments contaminated with blood.

9-101 Persons infected with HIV or at risk of infection with HIV should inform those persons who might be at risk of acquiring infection from them in the course of specific interactions. Specifically this includes: informing sexual partners and informing health care providers (doctor, dentist, nurse, and others).

9-102 Any provider of counseling and support to HIV-infected individuals should incorporate these principles into the information and support provided.

9-103
3-45 If, in the process of providing health care, a health care worker is exposed to the blood or body fluids of any patient, the health care worker has the right to know the infection status of that individual. Consent agreements obtained in the traditional health care provider/patient context will normally provide for this. In the unusual case of denial of consent, competent medical authorities should make the determination whether testing should be done and, if done, should note the rationale in the medical record.

Ethical Behavior of Others to Those Infected

In addition to the basic principle of nonmaleficence, our society values a respect for the liberty and dignity of each human being. The Commission has seen and heard examples of instances in which HIV-infected individuals were not accorded this basic respect by other citizens. As many witnesses before the Commission so eloquently expressed, the degree to which we are able to show respect, compassion, and concern for those who are infected or ill reflects the nature of our belief in human dignity and our own self-respect.

Violence against those perceived to carry HIV, so-called "hate crimes," is a serious problem. The Commission has heard reports in which homosexual men in particular have been victims of random violent acts that are indicative of some persons in society who are not reacting rationally to the epidemic. This type of violence is unacceptable and should be condemned by all Americans.

Obstacle to Progress

- There have been too many examples of discrimination, disrespect, violence, and inhumane treatment of persons infected with HIV by other members of the community.

RECOMMENDATIONS

9–104 All human beings deserve respect and preservation of their dignity in interactions with other human beings. HIV-infected persons are no exception to this basic ethical rule.

9–105 Violent acts against individuals with HIV infection or those perceived to carry HIV should be prosecuted to the fullest extent of the law.

CHAPTER TEN: FINANCING HEALTH CARE

Equitable financing of the HIV epidemic has been one of the greatest challenges placed before our health care delivery system. This epidemic has magnified flaws in the methods and mechanisms of the health care financing system in this country and magnified the impact on the delivery of quality care and services.

The Commission believes that the financing issue is one of the most difficult problems of the HIV epidemic. It is not easy to answer the questions about treating AIDS and HIV infection apart from other devastating sicknesses and diseases. If we can make changes in our financing system, do we do it only for those with HIV or do we do it for everyone? Allocating limited health care resources when the needs are so great presents a significant challenge.

The catastrophic financial impact that HIV infection has had on the personal lives of many was shared with the Commission during four days of public hearings. Persons with symptomatic HIV infection testified on the obstacles they must overcome when becoming ill as a result of HIV: the constant fear of losing a job and thereby a means of paying for health insurance; a daunting number of forms to be filed for various assistance programs and, very often, a long waiting period before receiving benefits, if at all; and the painful process of "spending down" -- using up most resources on medical bills if insurance is unavailable and income and assets are too high -- in order to qualify for Medicaid benefits. The obstacles faced by these persons point out the limited access to quality care, as well as the limitations of financing illness care in general across the nation.

Our current pluralistic approach to financing health care involves a combination of private and public funding. A person with HIV infection pays for care either out-of-pocket, through private health insurance, or through the public health system involving either Medicaid or Medicare.

Medicare provides health insurance benefits for persons over age 65 and qualified disabled persons while Medicaid provides medical services for the needy and medically needy. For a disabled individual to qualify for the Medicare program, a 24-month waiting period (which may total 30 months or more when disability waiting periods and administrative processing time are taken into account) must be completed while receiving a Social Security Disability Insurance benefit. For Medicaid health coverage, generally the individual must be receiving benefits under either Aid to Families with Dependent Children (AFDC) or Supplemental Security Income (SSI) programs, or must "spend down" on medical bills according to individual state requirements.

Section I. Financing Comprehensive Care

In the public hearings on finance, the Commission addressed the problems of equitable financing of care for persons with HIV infection and discovered linkages with the broader issues of financing our health care system. The issues brought to the surface by the HIV epidemic have been part of our health care financing system for a long time: the impact of catastrophic illnesses; increasing costs of inpatient services (including funds for recruitment and retention of nurses); lack of alternatives to hospital care; and inadequate reimbursement mechanisms.

For example, the costs for treating a person with symptomatic HIV infection are high, but are comparable to other high-priced treatments, such as those for cancer or heart disease. Hospitals are not adequately reimbursed for care provided to those with HIV infection, but this is true for many other illnesses. Cost-effective alternatives to hospital care in general should be encouraged, particularly for persons with HIV infection, but financial incentives are generally lacking to generate the appropriate level of services.

A number of factors, however, set apart the HIV epidemic from other health care crises. One factor is that the overall costs to the nation both in terms of medical care and lost productivity are large and will continue to grow as the prevalence of HIV infection increases. This disease has struck many persons in their prime earning years, challenging the established approach for financing care for episodic illnesses and creating the potential for an imbalance in the system over the long term. In addition, a few geographical areas are harder hit than other parts of the country. While this situation has created an immediate funding crisis for large urban areas, the impact of the HIV epidemic on the financing of care is beginning to be more broadly felt throughout the nation.

Costs of Care

The costs of inpatient care for a person with AIDS are high, but are comparable to other high-cost medical conditions or illnesses. Current estimates of lifetime hospital costs for a person with AIDS are under $100,000 and annual treatment costs are approximately $40,000. In comparison, the estimated costs of a liver transplant are $175,000, of end-stage renal disease $158,000, and of a heart transplant $83,000.

Nationwide, the costs for the provision of medical care to persons with AIDS are projected to increase from about $1.1 billion in 1985 up to $8.5 billion in 1991. As a proportion of United States personal health care expenditures, medical care costs for treating AIDS will grow from 0.2 percent to 1.4 percent over the same period. Total costs to the nation associated with AIDS -- personal medical care and services, lost income, decreased consumption, and insurance payouts -- were approximately $8.7 billion in 1986 and are projected to reach a total of $66.5 billion in 1991, based on the projection of 173,000 cases of AIDS.

To put these costs in perspective, catastrophic illnesses cost the nation about $56 billion each year. If taken together, heart disease, stroke, cancer, and motor vehicle accidents account for about 20 percent of national medical expenditures. Total national health care expenditures exceeded an estimated $425 billion in 1986.

A major obstacle to encouraging more cost-effective, out-of-hospital care has been a lack of data on actual cost savings for such care. We have heard testimony that case-managed care, used in determining appropriate levels of care, can save as much as $12 for every one dollar spent on AIDS case management. Better data on the savings of out-of-hospital care should be available after June of this year when the Health Resources and Services Administration (HRSA) will be evaluating the costs of outpatient and clinic services to determine cost-effectiveness of patient support services.

Reimbursement for Care

Both public and private health insurance reimbursement is based on the expected costs of a service. If the individual has no health insurance or inadequate coverage, the unreimbursed costs must be paid out-of-pocket or the hospital and other patients incur the cost for provision of service. Unreimbursed care in public hospitals must eventually be compensated by the community through general revenues.

While reimbursement has been inadequate from both public and private payers to hospitals for the costs of treating persons with HIV infection and AIDS, the problem is felt most acutely in the public hospital systems, particularly in the South. The average national inpatient cost of caring for a patient with AIDS has been estimated at about $630 per day. The Medicaid reimbursement rate in the South, however, averages about $282 per day and in other regions of the country about $500 per day.

Reimbursement has also been inadequate in promoting care in alternate, more appropriate settings. The Medicaid program, the primary payer for most individuals with AIDS, is restrictive in reimbursement levels for certain types of facilities. For instance, care for a person with AIDS in a long-term care institution can cost an estimated $200 per day, but in most states

Medicaid reimburses only about $50 per day. State Medicaid programs also do not adequately cover outpatient services needed by community-based programs to help individuals with AIDS.

Provision of Services

A major problem in the provision of services for persons with AIDS is that public and private payers set limits on the extent of services that are covered and in many instances the excluded services are those that are most relevant in the care of persons with AIDS. Federal law requires that the state Medicaid program provide certain services, such as inpatient and outpatient care, physician services, and skilled nursing services at home for eligible persons. The states then have the option to provide other services, such as home health care aides, clinic services, and personal care services.

In order to encourage more innovation in providing health care for persons with AIDS, several states have activated additional options under their Medicaid programs. New Jersey and New Mexico were the first two states in the country to use a waiver authorized under Section 2176 of the Omnibus Budget Reconciliation Act of 1981. This waiver allows states to provide cost-effective home and community-based care for persons with AIDS. California applied and was recently approved for the Section 2176 service waiver. Exercising other options, New York has started a system for providing a range of care for AIDS patients and is collecting data on the costs of this care. This model program which could be used or modified in treating other illnesses or medical conditions demonstrates how payment can be tied to the delivery of an appropriate range of services.

States should continue to explore the set of options at their disposal under the Medicaid waiver program to provide appropriate, cost-effective services to persons with AIDS and extend those services to all persons with symptomatic HIV infection. We have heard testimony, however, indicating that significant administrative problems exist in obtaining approval for these waivers. The waiver review process is burdensome and includes administrative requirements, which may be unnecessary.

Another problem in the provision of services is a scarcity of resources available for dealing with HIV infection in both the inpatient setting and in providing community-based, out-of-hospital care, particularly in areas that are disproportionately affected by HIV. While there are excess hospital beds in many parts of the country, New York City is currently experiencing a shortage of beds, and it projects a need for approximately 1,300 to 1,500 beds by 1991 to care for AIDS patients. In these hard-hit areas, there is an inadequate provision of long-term care, a lack of capital funding to provide facilities, and/or a lack of treatment facilities for intravenous drug abusers.

In addition to providing care for those with acute illnesses, most public hospital systems provide much of the acute care for drug abusers with HIV-related illnesses. In the New York City Health and Hospital Corporation system, 75 percent of the people with AIDS are drug users or the children of drug users.

The issue of financing services for persons with HIV infection brings into focus another problem inherent with funding care for episodic illnesses -- that of linking the reimbursement stream and licensure requirements of a facility to the general health status of the residents of a facility. Some facilities can provide services, such as drug treatment, testing, counseling, information, and education, while also providing a place for patients to live. A continuous funding stream must be available to support care for individuals with HIV infection and to reimburse the facility adequately for costs. This is particularly true in the case of HIV-infected children who are abandoned in hospitals -- boarder babies. These children could be better cared for in alternative residential settings, such as foster homes or group homes. Current state licensing, Medicaid, and Supplemental Security Income regulations restrict support for these types of facilities because the care being provided is in a setting other than the currently allowed, fully licensed Skilled Nursing Facility or Intermediate Care Facility.

While the Commission recognizes that some suggested major adjustments will not happen in the near future, the current situation calls for immediate action to provide funding necessary to help the hardest hit areas and provide care for people in desperate need of assistance. This would mean providing targeted assistance in the form of block grants to the hardest hit areas and encouraging cost-effective care through enhanced reimbursement from the federal government. The administrative hurdles of the waiver programs should also be reviewed and trimmed back to encourage innovative programs of care as soon as possible.

In the medium term, the data being collected currently and under proposed demonstration projects will provide the information and experience upon which a long-term strategy can be developed and implemented.

Obstacles to Progress

- Data is lacking on the costs of treating AIDS and HIV infection, the cost-effectiveness of various care modes, and the sources of payment.
- There are limited community support systems for HIV-infected persons to facilitate out-of-hospital care and to provide emotional and financial assistance.
- Incentives and supporting regulations are lacking for continuity of care, for appropriate, cost-effective alternatives to inpatient care, and for adequately managed care starting from initial diagnosis.
- The private and public health care reimbursement systems emphasize institutional care and are unresponsive to alternative health services, which may be more desirable from the patient's perspective and more cost-effective over the long term.
- Incentives are lacking for development of alternative care facilities. Administrative roadblocks exist for expansion of housing, and funding streams are inadequate to support existing facilities.

RECOMMENDATIONS

Financing Cost-Effective Care

10–1 The Health Care Financing Administration should continue actively to encourage states to take advantage of a number of options available in their Medicaid programs. These options include, but are not limited to, amending plans to provide case management services targeted to certain groups such as persons with HIV infection; adopting hospice benefits useful to persons with AIDS; applying for home and community-based services waivers (Section 2176 waivers); applying for "freedom of choice" waivers permitting case management service mechanisms and innovative reimbursement methods to be used for services to persons with HIV infection; and developing special incentive payment rates for services to persons with AIDS and other patients with high-cost care requirements.

10–2 The Health Care Financing Administration (HCFA) should change the Medicaid waiver review process, streamlining and eliminating aspects of the application process which delay approval, expanding the availability and size of the waiver program, and providing more flexibility for testing innovative treatment alternatives. To this end, HCFA should convene a meeting of state officials or spokesmen, including state Medicaid directors, in order to discuss specific changes in the waiver review process as well as a minimum package of benefits that should be reimbursed for care of symptomatic HIV patients.

10–3 The Health Care Financing Administration, in conjunction with the Health Resources and Services Administration, should encourage additional demonstration projects of reimbursement mechanisms to providers for cost-effective care of very ill patients, including experimentation in capitation, prepaid care, and use of case management by various providers. The results of these demonstration programs should be compiled and distributed to federal and state officials for consideration in legislation and program changes.

10–4 Private health insurers should begin reviewing and revising the services eligible for reimbursement and the rates of reimbursement to cover adequately program costs, such as home health care, focusing on appropriate and cost-effective services for individuals with HIV-related illnesses.

10–5 In light of some states' experiences with Diagnostic Related Group (DRG) reimbursement for HIV-related illnesses, the Health Care Financing Administration should consider whether to create a system of well-defined Medicare and Medicaid DRGs which takes into account the full costs of caring for an individual with various manifestations of HIV infection, including the costs of implementing the Centers for Disease Control's Universal Infection Control Precautions.

10–6 The Health Care Financing Administration should establish a demonstration project which increases the federal Medicaid matching rate for states that give providers a higher rate for promoting long-term care, comprehensive home care, outpatient services, and case management of a full range of services, including coordination with other providers, to encourage cost-effective care for HIV-infected patients.

10–7 The Health Care Financing Administration should amend federal Medicaid regulations to allow non-hospital-based drug rehabilitation programs in a residential setting to receive federal reimbursement and to promote expansion of residential programs. This may entail exempting these programs from inclusion in the definition of Institutions for Mental Diseases.

10–8 States should re-evaluate Medicaid and Supplemental Security Income reimbursement levels for supportive housing programs for people with AIDS and review how facilities are licensed in order to provide in a residential setting the level of care needed for homeless persons.

10–9 The Department of Housing and Urban Development should increase funding to encourage state and local governments, in concert with foundations and private enterprises, to establish programs to subsidize supportive housing for persons with HIV infection.

10–10 2–9 The Health Care Financing Administration should encourage states to provide exceptions to limits on state Medicaid payments for providing necessary inpatient care for infants in hospitals with disproportionately large Medicaid patient populations.

Targeted Assistance

10–11 2–11 The Health Care Financing Administration and the Health Resources and Services Administration should institute a program of special project grants to private and public agencies for the development or expansion of outpatient services and home care.

10–12 The Health Care Financing Administration, together with the Health Resources and Services Administration, should establish a stop-loss provision for Medicaid which would provide block grants to states when the proportion of Medicaid funds spent on AIDS care exceeds a predetermined level, similar to the provision under the Supplemental Unemployment Benefit Program.

Section II. Financing Health Insurance Coverage

Access to adequate health care has been hindered by a lack of health insurance in general. As many as 35 million Americans may be without health insurance coverage. In one public hospital in Texas dealing with a large proportion of AIDS patients, fully 75 percent of its patients had no health insurance.

The lack of adequate health insurance among persons with AIDS is an even greater problem. The uninsured make up a larger proportion of persons with AIDS than among the general population (20 percent vs. 16 percent) and persons with AIDS have a much greater reliance on Medicaid than the general population (40 percent vs. nine percent). Private health insurance and Medicaid cover about the same proportion of funding for individuals with AIDS (40 percent), but private insurance coverage among the general population is much higher (62 percent). This situation will become worse as the proportion of intravenous drug abusers among persons with AIDS continues to rise and if private insurance limits coverage for persons with AIDS.

The reasons vary for the lack of adequate or any health coverage among persons with HIV infection: small employers may be unable to provide affordable health benefits; employees losing their jobs may be unable to pay high premiums to continue benefits or may not be able to obtain other coverage as a result of preexisting illness exclusions; employees may have inadequate health coverage from self-insured companies which are exempt from state insurance regulations under the Employee Retirement Income Security Act (ERISA).

Inadequate coverage still persists, notwithstanding the provisions established under the Consolidated Omnibus Budget Reconciliation Act (COBRA). COBRA allows an employee and his or her dependents to continue employer-provided coverage for 18 months after losing his or her job if the employee pays the premium at a cost of no more than 102 percent of the employer's premium. This enables the former employee and dependents to continue private health insurance for at least part of the 24-month waiting period to qualify for Medicare and avoids the problem of spending down to qualify for Medicaid. The Commission believes that the provision of adequate health insurance benefits through COBRA can be accomplished with a program of financial assistance to the disabled person unable to afford the high premiums until qualifying for Medicare and this would be preferable to a reliance on the Medicaid program.

The financial impact of the HIV epidemic on the employer is unclear, particularly on the ability of the small business to provide health insurance benefits. Information is not available on the extent to which small businesses have been turned down for coverage or have experienced large increases in insurance premiums because of AIDS cases among employees.

The Commission has heard testimony indicating that our pluralistic approach to financing care, involving a mix of public and private resources, can provide adequate health insurance coverage if some adjustments are made. Others have suggested that, short of a national health insurance system, there could only be a patchwork approach to financing care for persons with HIV infection. In light of the connection between the lack of adequate health insurance for persons infected with HIV and the lack of adequate health insurance in the general population, the Department of Health and Human Services should evaluate the problems of financing our overall health care system and determine what changes should be made to provide full access to comprehensive health care. There is a need to reinforce private health insurance coverage, making it more comprehensive while pursuing innovative approaches to financing care.

State uninsurable risk pools, now operating in 15 states and under consideration in 13 others, have provided a partial solution to comprehensive coverage of the uninsurable, but they face several problems. Experts have testified that the deficits in most of these pools are disproportionately financed by the small and medium-sized firms paying for group health insurance since many of the larger companies are self-insured and thereby exempt from contributing to high-risk pools. In addition, high premiums and coinsurance charges preclude many of the individuals in need of this health coverage from participating. On the other hand, such programs in some states are threatening to strain state budgets.

A reinforcement of the current pluralistic system, while adjustments are made and existing gaps in coverage are filled, should enable all persons to gain access to necessary care.

Obstacles to Progress

- With the large number of uninsured persons and the diversity of the population needing comprehensive care, the financing of health care costs in general is currently inadequate and will continue to become an increasingly greater problem as the number of persons progressing to symptomatic HIV infection increases.

- Health care benefit eligibility and coverage provisions are inadequate for HIV-infected persons losing employment, applying for individual coverage, or near or below the poverty line.

- A pluralistic approach involving public and private financing of HIV-related care is being jeopardized by inadequate insurance coverage of HIV-infected individuals.

- Information is not available on the impact of AIDS or HIV infection on the insurance costs of small businesses.

- The potential of Medicaid financing for the care of persons with AIDS varies substantially according to where the person lives because basic eligibility levels and the "spend down" provisions associated with Medicaid are established by the state and vary enormously.

- The potential of Medicare financing for the care of persons with AIDS is limited because of the two-year waiting period to qualify for Medicare benefits.

- The funding for health care coverage of persons with uninsurable risks is not equitably shared, and costs incurred by individuals in state uninsurable risk pools are substantial as are the pool losses, while the coverage is limited.

RECOMMENDATIONS

10–13 The Secretary of Health and Human Services, in conjunction with an independent outside body, should evaluate our current system of health care financing and recommend changes needed to achieve access to and provision of health care for all segments of our society.

10–14 In the course of the evaluation described in (10–13), consideration should be given to two major options:

- Extending the COBRA provision beyond the 18-month period for employee-paid, group rate premiums from the employer's health insurance coverage to provide adequate coverage for the former employee until qualifying for Medicare. Consideration should be given to providing federal assistance to help pay the private insurance premium for persons unable to pay the full premium.

- Decreasing the waiting period for qualifying for Medicare from 24 months to 12 months in order to provide health insurance coverage after the 18-month COBRA provision has expired. Consideration should be given to providing federal assistance to help pay the private insurance premium for persons unable to pay the full premium.

10-15 The federal government should experiment with providing tax incentives for insurers to provide community-rated, open-enrollment policies. The federal government also should make available refundable tax credits to be used for purchasing insurance by people who do not receive any employer health insurance and provide premium subsidies for private health insurance for persons unable to pay the full premium.

10-16 The federal government should conduct a study examining the extent to which HIV has presented special underwriting problems in the small group health insurance market.

10-17 The federal government should encourage all states to enact a qualified state pool for medically uninsurable individuals with the following provisions:

- The federal government should experiment with providing technical assistance to states to ensure adequate coverage, financing from a combination of private and public sector funds, adequate provision of benefits, and mandated case management;

- The federal government should consider amending the Employee Retirement Income Security Act (ERISA) to include self-insured plans in pool funding; and

- The federal government should consider establishing a risk pool fund, administered by a non-profit or limited-profit corporation acting as a reinsurance organization and should be the source of stop-loss subsidies for state risk pools. The Health Care Financing Administration should evaluate the various sources of public and private financing that would be available for this fund to cover administrative losses and to subsidize costs to patients.

10-18 The federal government should require that all patients using 50 percent or more federal dollars for their care participate in a case-managed system.

Medicaid

10-19 The Health Care Financing Administration should consider requiring states to move toward a minimum Medicaid eligibility floor at 50 percent of poverty within two years and implement a phased-in plan for moving to 100 percent of poverty, giving states the option of further raising the income threshold for the disabled.

10-20 The Health Care Financing Administration should consider amending regulations to enable individuals to retain eligibility to Medicaid benefits, although entitlement to Supplemental Security Income benefits may be lost when becoming entitled to Social Security Disability Insurance benefits.

10-21 States should consider enacting medically needy provisions under their Medicaid programs, if they have not done so.

10-22 States should consider expanding their medically needy programs by allowing low-income individuals to pay an income-related premium for the purpose of buying into Medicaid.

10-23 The Health Care Financing Administration should re-evaluate the regulations which stipulate eligibility requirements for hospice care under the Medicaid program and consider the impact of waiving the six-month prognosis requirement for persons with AIDS.

Social Security

10-24 The Social Security Administration should consider proposing a statutory change allowing individuals with symptomatic HIV infection, as well as other disabled persons, to work when they are healthy enough to resume working with earnings offsetting a percentage of benefits, but without disqualifying them for eligibility to their Social Security Disability Insurance benefits, much like the provision of the Supplemental Security Income program under Section 1619 of the Social Security Act.

10-25 Those agencies providing assistance to HIV-infected individuals (such as the Social Security Administration and the Health Care Financing Administration) should consider streamlining the processes of enrollment in programs and reducing the bureaucratic red tape.

CHAPTER ELEVEN: THE INTERNATIONAL RESPONSE

The human immunodeficiency virus has presented the world community with the greatest public health threat of this century. It was not until 1982 that researchers in France and the United States isolated and identified HIV -- when it already had a firm foothold in four continents. Today, 136 nations of the 175 countries reporting to the World Health Organization (WHO) have recorded cases of AIDS. Moreover, it is estimated that between five and ten million people worldwide are currently infected with HIV, with approximately one and one half million of these in the United States.

Two years ago, world leaders acknowledged that the epidemic required a global strategy to combat the spread of the virus. The 1986-87 World Health Assembly charged WHO with providing leadership in the international fight against AIDS. At WHO's request, the Centers for Disease Control (CDC) detailed Dr. Jonathan Mann to WHO to serve as Director of the Global Programme on AIDS (GPA).

The following year, the World Health Assembly unanimously endorsed WHO's Global Strategy for the Prevention and Control of AIDS. Five months later, in October 1987, the Global Strategy was presented to the United Nations General Assembly, which adopted a resolution of support for GPA's leadership role in the worldwide program of prevention and control. WHO/GPA has provided assistance to many nations, enabling them to prepare national HIV plans to combat the spread of the virus, thereby becoming eligible for financial assistance from the international body. Other United Nations organizations, including UNICEF, are contributing their expertise and resources to support components of GPA. The strengths of WHO and the United Nations Development Program (UNDP) are now being combined in the UNDP/WHO Alliance to Combat AIDS in developing countries. UNDP Resident Representatives have begun collaboration with GPA to implement, monitor, and evaluate national program support activities.

Further, GPA in conjunction with the UNDP is coordinating the Global Blood Safety Initiative to safeguard blood supplies from the HIV and other pathogens. Under this initiative, a broad consortium of governmental and nongovernmental agencies will work together to establish blood transfusion systems capable of implementing adequate quality control procedures on a routine, sustainable basis. The Commission strongly supports placing a high priority on the objective of a safe blood supply -- because it is achievable, and the transmission of this virus through blood products is preventable -- independent of development of a vaccine or successful therapeutic agent.

The Commission supports and commends WHO and the GPA for its leadership role and comprehensive program of prevention, treatment, and control of this disease. As the nation with the largest number of reported cases of AIDS in the world, as a major contributor to WHO and GPA, and as a country with extensive scientific resources, the United States has the motivation, the commitment, and the resources to support GPA.

The United States should develop its own long-range international plan of action which includes encouraging all multilateral organizations in which it has membership to lend full support to this global effort. The United States bilateral strategy should include full cooperation with GPA in providing aid to designated recipient countries within the context of their national HIV programs. One of the most serious deficiencies developing nations face in endeavoring to combat the epidemic is the lack of infrastructure (e.g., trained manpower, technical equipment, and basic medical supplies) in their health care delivery systems. The United States should therefore maximize the effectiveness of its bilateral aid by providing technical assistance and training to host country nationals, which will assist in the development of infrastructure and complement the programs of GPA.

It is essential that all United States agencies and organizations work together to assure maximum effectiveness and coordination of financial and technical resources. The Agency for International Development (A.I.D.), which is responsible for directing the economic assistance activities of the United States in the developing world, should develop a coordinated program of support with GPA to lessen the impact and control the spread of the virus. The research community must also be encouraged to collaborate with their colleagues abroad, sharing resources and information and avoiding duplication.

In the establishment of public health programs in developing countries, just as in domestic programs, knowledge of and experience with local cultures and habits is vital, particularly in the areas of education and behavior. The United States has an extensive network of non-governmental organizations, including private voluntary organizations, which have experience in international public health programs and are well positioned to transfer technology and assistance to developing nations. A.I.D. should be directed to place much greater emphasis on the use of these organizations to implement effective research, education, and control programs at the grassroots level in developing countries.

Section I. World Health Organization/Global Programme on AIDS

WHO/GPA Assistance Programs

The Commission endorses the strong leadership of the World Health Organization's Global Programme on AIDS in bringing together the international community in a collaborative effort to address the HIV pandemic. The Commission recognizes GPA and its Director, Dr. Jonathan Mann, for the enormous progress that has been made in enhancing the global understanding of the epidemic and stimulating a global response. The Commission supports the work of GPA in assisting governments to develop national HIV plans. The Commission believes that the United States, as a contributor to multilateral and bilateral programs, should provide increased financial and technical support to GPA to develop programs which provide a focus for the world community.

Obstacles to Progress

- The health care infrastructures in many countries most affected by HIV have inadequate financial and technical resources. Public health officials in these countries are confronted by critical shortages in trained personnel, supplies, equipment, and facilities.

- Lack of coordination among donors may place an additional burden on scarce managerial personnel in many developing countries.

- Competing donors may generate an undesirable sense of rivalry or multiple agendas with divergent objectives.

- Many development experts and host country health officials fear that the current focus on prevention and treatment of HIV disease may drain financial and technical resources away from existing health care programs, such as expanded programs of immunization, which are immediately critical to the well-being of the entire population.

- Some countries have been reluctant to collect and disseminate their own data on HIV prevalence because of a potential negative impact on tourism or development funding.

- Carefully coordinated and controlled international programs do not always provide the flexibility and creativity necessary to discover the best alternative means to address the HIV pandemic at the local level.

RECOMMENDATIONS

The United States gives financial support to both the World Health Organization and GPA, providing more than 20 percent of the WHO budget and contributing $22 million to GPA, with $15 million in 1988 alone. As a member nation of WHO and contributor to GPA, the United States, therefore, has a voice in development of WHO/GPA programming.

11-1 Recognizing that the United States has paid in full its 1987 assessed contribution to the World Health Organization (WHO), the United States government should continue direct contribution of sufficient resources to the WHO's Global Programme on AIDS (GPA). In addition, the United States should make a long-term commitment of support for the GPA to enhance its capacity for long-range planning.

11-2 The United States contribution to the World Health Organization (WHO) should receive special consideration and be exempt from restrictions placed upon contributions to other specialized agencies of the United Nations. WHO has a superior record both in the proper use of its funding and the elimination of political issues from its agenda. In the event there is any change in the manner or direction in which WHO fulfills its responsibilities, appropriate action could then be taken.

11-3 The World Health Organization's Global Programme on AIDS should continue its efforts to develop national HIV plans, working closely with host-country ministries of health to ensure a sense of national ownership, proper budgeting of recurrent costs, and coordination of donor agency contributions. This collaborative process will help ensure that responsibility for these programs rests with national governments from their inception. National HIV programs will be most effective if they are integrated into the primary health care network and do not divert scarce resources from the many other health problems facing developing countries.

11-4 The World Health Organization's Global Programme on AIDS, through their own resources and those of donor nations, should strengthen and expand training and technical assistance to host country nationals to enable them to implement and sustain national health care programs. Assistance programs must address not only HIV, but also the building of the health care infrastructure.

11-5 The World Health Organization's Global Programme on AIDS should give specific technical assistance to national institutions in those areas in which it has a decided strength, such as epidemiologic surveys, surveillance, health promotion, blood safety, and laboratory diagnosis, to enable them to develop their own capacity to sustain these programs. Additional programs and services should be carried out by bilateral donors and other organizations with skills in such areas as education, patient management, and counseling, utilizing the coordination mechanism of the national HIV committees.

11-6 The regional programs of the World Health Organization's Global Programme on AIDS (WHO/GPA) should be enhanced by making it possible for a broader range of interested groups and donor organizations to develop a concerted approach to this complex epidemic. WHO/GPA should encourage countries to turn to bilateral donors and nongovernmental organizations for assistance in developing HIV-related education and counseling programs.

11-7 Financial and technical resources need to be targeted not only to those countries in which current needs are acute, but equally to those countries where low prevalence rates indicate that education programs may be most effective. A small investment in these low prevalence areas now will result in a greater gain in the future through the containment of HIV.

11-8 Programs must respect human rights. All countries share the dual responsibilities of protecting the rights of the healthy as well as those infected with the virus. Responsible behavior can be undermined by a climate of fear and discrimination. When discrimination occurs, the capacity to fight the disease is effectively reduced, threatening public health.

11-9 The Commission supports the proposal of the World Health Organization's Global Programme on AIDS to establish coordinated biennial donor evaluations to diminish the burden of constant evaluations on in-country program administrators and project staff.

WHO/GPA International Research Efforts

Obstacles to Progress

- There is a lack of uniformly collected data on scope and prevalence of HIV due to lack of resources, both human and technical, to collect such data.

- Because of concern over intercultural and international stigmatization and discrimination, there is resistance to sharing existing prevalence information.

- Insufficient epidemiological or behavioral research is underway to provide basic information required to test the effectiveness of current interventions. Neither has operations research been undertaken to evaluate prevailing responses to the epidemic.

- There is a lack of common research terminology and inadequate capacity to disseminate research objectives and results.

RECOMMENDATIONS

11-10 The World Health Organization should continue its efforts to gather, summarize, and publish all data on HIV for member governments. A collaborative electronic media network for information exchange should be established so that feedback can be shared on epidemiological data as well as effective protocols. This should include shared information about drugs under investigation internationally.

11-11 The World Health Organization's Global Programme on AIDS should continue to provide the forum for the exchange of current scientific information. It is important that these exchanges bring together national policymakers, representatives of research communities and working level personnel. Provision should also be made for international coordination of research efforts between both the medical and social science research communities.

11-12 To facilitate these critical exchanges of information, universally standardized terminology should be defined and used. In recognition of this need, the World Health Organization's Global Programme on AIDS should convene an international consultation to develop this terminology.

11-13 Research into the development of inexpensive, fast-response tests for detecting HIV infection should be continued.

11-14 The World Health Organization's Global Programme on AIDS should play a leadership role in developing and implementing protocols for international vaccine field trials.

11-15 International adoption of standardized clinical staging systems is needed so that comparisons can be made in the natural history of infection and in treatment regimens.

11-16 Epidemiological and behavioral research is required to test new technologies and alternative approaches to the containment of HIV as they are identified. Comparative analysis of this research would facilitate identification of optimal methods of intervention.

11-17 Multidisciplinary international HIV research centers are needed in developing countries. Each center should have sufficient resources to support teams of international and national scientists to make comprehensive studies of HIV in regional settings.

Section II. Other Multilateral and Bilateral Programs

The Commission strongly supports the recent joint efforts of the United Nations Development Program (UNDP) and WHO. The experience of UNDP in multisectoral, socioeconomic development, combined with the health policy, technical and scientific expertise of WHO, will support governments of developing countries in initiating, implementing, monitoring, and evaluating national HIV prevention and control plans.

The Commission commends the World Bank and other international development banks for their active recognition that a basic standard of health for all is a fundamental goal of development programs. Because prevention of disease can stimulate overall productivity, basic preventive and curative services need to be extended to the entire population in developing countries to reinforce efforts to combat a wide range of diseases, including HIV infection.

Non-governmental organizations (NGOs), especially private voluntary organizations (PVOs), are potentially valuable resources in the struggle to slow the spread of the virus because of their close association with local communities and their ability to handle culturally sensitive issues. Many NGOs and PVOs have a proven track record in community acceptance for health delivery, community-based development programs, trained local staff, and strong links to national organizations and national policymakers. Some have attained a high level of expertise in training and mobilizing professionals and lay persons in sensitive tasks, implemented under difficult circumstances.

Private organizations in collaboration with indigenous PVOs could implement national policies and stimulate alternative community-based responses to the epidemic. Private funding would allow NGOs the flexibility to develop innovative alternative approaches to the problems at hand.

Bilateral Assistance Programs

Consistent with United States foreign policy objectives, the primary mandate of A.I.D. is to help developing countries seeking United States assistance realize their aspirations. The fulfillment of this mandate requires that A.I.D. draw heavily on the technical staff of other federal agencies, universities, PVOs, and commercial contractors.

Obstacles to Progress

- United States policy for bilateral and multilateral assistance still lacks the coordinated strategic planning required of a significant partner in GPA. A.I.D. has difficulty in clearly defining its long-term objectives to contain the spread of HIV.

- Because of concern for the federal deficit, A.I.D. is reluctant to request the technical or financial resources required to achieve long-term goals. The funding designated for HIV-related programs worldwide is insufficient to meet requests for assistance. Other A.I.D. accounts may be drawn down to fund HIV components. If other A.I.D. funding is available for use in HIV-related programs, clarification for the provider community is necessary.

- A.I.D.'s pre-existing commitments of anticipated funds have resulted in limited funding available for PVOs that have the experience to assist in worldwide HIV programming.

- Budgetary restrictions impede A.I.D.'s ability to obtain sufficient numbers of technically qualified personnel with health expertise in HIV, adding to the problem of supervision and coordination of assistance directed at controlling the global epidemic.

- Biomedical and behavioral research has not yet been extensive enough to provide clear guidelines for appropriate interventions. Interventions now being used to stem the spread of the epidemic have not been evaluated.

- Improvement is needed in infrastructure and health care delivery systems to sustain development efforts.

RECOMMENDATIONS

11-18 The Agency for International Development (A.I.D.) should develop a five-year strategy which outlines the main goals of the United States in the global effort to address the HIV epidemic. The plan should include objectives for support of the Global Programme on AIDS and the development and implementation of bilateral assistance programs which contribute to national HIV programs and which complement those of other donors. If more funding and additional technically qualified health related personnel are needed, representatives of A.I.D. should request them. Current limited funding for critical health programs should not be diverted.

11-19 The Agency for International Development should concentrate its HIV-related assistance on clearly defined programs in which it has pronounced expertise. Particular emphasis should be given to those programs which can be sustained and copied.

11-20 The Agency for International Development should review existing service delivery programs in child survival, maternal and child health, immunization, and family planning to identify areas where HIV-related components could be added to reach target populations.

11-21 Current support for international health projects needs to be expanded to include basic support for health care infrastructure and delivery systems. This would provide a solid basis for all HIV prevention and care programs.

11-22 Bilateral assistance should emphasize the education and training of local health care workers so they can train others in the community as well as provide services.

11-23 The Agency for International Development should increase its support for improved epidemiologic data collection and modeling for a better global understanding of the dynamics of the epidemic in all parts of the world. This work should be coordinated with the World Health Organization's Global Programme on AIDS, and the database and modeling should be available to the international assistance community.

11-24 United States bilateral assistance should include special attention to the Western Hemisphere and the Pacific Rim in light of immigration, tourist, commercial, and strategic considerations.

11-25 Private sector organizations should join the public sector in support of research projects and field programs.

11-26 Qualified private voluntary organizations should be identified and encouraged through the commitment of funds of the Agency for International Development to develop programs of health care service

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delivery, education and research that support and complement local government and national priorities.

11-27 Non-governmental organizations (NGOs) and private voluntary organizations should, when possible, undertake joint projects with host country NGOs, providing technical assistance and training as requested and assisting them to identify local needs, develop effective responses, and monitor outcomes.

11-28 The Agency for International Development (A.I.D.) should clarify the sources and availability of additional funds within other A.I.D. accounts for HIV-related programs. Non-governmental organizations, including universities and private voluntary organizations, should be advised of the availability of these funds and the method of access to them.

11-29 The Agency for International Development (A.I.D.) should identify processes to allow for regular review of all bilateral HIV programs to assess progress, recognize innovations, respond to resource and program gaps, and foster economy and efficiency. A.I.D. should establish a forum for facilitating communication among non-governmental organizations and federal agencies.

Peace Corps

Throughout its history, the Peace Corps' most effective programs are those which have been developed at the request of and in close collaboration with host country governments. The Peace Corps is continuing to explore innovative nontraditional ways of deploying volunteers and is currently identifying opportunities for collaboration with other assistance organizations. Through its unique and well-established ability to provide education, the Peace Corps should expand its current capacity to assist host countries to implement their HIV prevention programs.

RECOMMENDATIONS

11-30 The Peace Corps should develop a portfolio of available HIV-related training and assistance programs to be offered to host country governments that have requested assistance. These programs should complement existing ones. The Peace Corps should receive supplemental funding to finance these programs.

11-31 Using the best health education techniques available, volunteers should respond to requests for assistance by working with host country personnel to integrate HIV education into a full range of curricula. In addition to teaching trainers to work with village level organizations, they should develop targeted education programs for specific hard-to-reach populations.

11-32 Volunteers should help strengthen existing health care services through the training of national health care workers in all specialties.

11-33 The Peace Corps, the United States Public Health Service, and non-governmental organizations should work collaboratively to avoid competition for resources and duplication of efforts.

Bilateral Research

The National Institutes of Health (NIH) conducts international research under the authority of the International Health Research Act of 1960. This Act authorizes NIH to "advance the status of the health sciences in the United States and thereby the health of the American people through cooperative endeavors with other countries in health research, health planning and research training." Similarly the Alcohol, Drug Abuse, and Mental Health Administration and the Food and Drug Administration conduct international research.

Obstacles to Progress

- There is an inadequate epidemiological data base to serve as the basis for targeting assistance programs. In addition, there is a dearth of reliable information on appropriate interventions required to combat the spread of HIV.

- The dramatic increase in federal funding for HIV research has not been accompanied by a proportional increase in federal staff positions to conduct or manage the research efforts to handle the current domestic obligations in HIV or to expand the international research effort. Current staffing is insufficient to respond to international requests for technical assistance in various types of research and programming which could have substantial benefits for our own control programs.

- Federal scientists are strictly limited in international travel, with no distinction made between travel to attend scientific meetings and travel to conduct or evaluate federally funded projects.

- An expanded international HIV effort for NIH will depend upon the presence of a critical mass of interested and capable scientists in the academic community -- both in the United States and in host countries. There are few academic institutions with the scientific expertise for HIV studies in developing countries and with the international experience and contacts to support large-scale, multidisciplinary HIV projects.

- Researchers are forced to spend substantial amounts of time writing proposals because of the current system of short-term grants and low funding levels.

RECOMMENDATIONS

11-34 As a part of the strategic planning process implemented by the Department of Health and Human Services a five-year plan should be developed outlining the research priorities and goals of the Department's research institutions. This should be done in conjunction with five-year plan of the Agency for International Development and the work of the World Health Organization's Global Programme on AIDS.

11-35 Research, epidemiological training, and control programs should have three basic components: collaboration, research training, and institutional support. The Department of Health and Human Services should establish a program to assist developing countries to improve the quality and capacity of laboratories and increase the number of epidemiologists capable of tracking the epidemic. Collaborative programs that combine research and training are an appropriate and effective means of strengthening capabilities of developing countries to deal with the HIV epidemic.

11-36 The federal government should establish an international HIV research support unit. Such a unit could coordinate efforts by the Agency for International Development, the National Institutes of Health, the Centers for Disease Control, and other public agencies, thereby responding more effectively to requests from other governments for assistance in research.

11-37 Full-time equivalent positions in the National Institutes of Health and the Centers for Disease Control should be expanded so these agencies could respond to international requests for technical assistance and enhance cooperation with the World Health Organization's Global Programme on AIDS.

11-38 Travel restrictions should be reevaluated to permit appropriate participation in international scientific meetings and to provide requested technical assistance.

11-39 Research grants should be awarded for three- to five-year periods at adequate funding levels.

11-40 Postdoctoral training fellowships should be established to enable social scientists and biomedical researchers to learn more about the socio-behavioral aspects of the epidemic.

Coordination in Drug Development

RECOMMENDATION

11-41 The United States, through the Department of Health and Human Services and the Food and Drug Administration, should develop a mechanism for working with other nations with similar drug development and control programs to accept their data leading to the approval of experimental drugs for HIV disease to be used in clinical trials.

HIV-2 Research

RECOMMENDATION

11-42 Research is needed to determine the clinical significance of HIV-2. Studies conducted in West Africa will be most useful in determining the effects of this virus where levels of infection in certain populations are already high. Continued research is needed to determine the natural history of HIV-2 and analyze its relationship to HIV-1.

Section III. Department of Defense

Because of the size and unique mission of the Department of Defense (DoD), it provides the nation with a critical source of much needed research on HIV. The Department has developed long-range comprehensive HIV programs which are reviewed periodically to ensure their adherence to current scientific information.

DoD has undertaken an extensive national HIV testing program providing important opportunities for epidemiological research that are nowhere else available in this magnitude. In addition, identifying HIV-infected individuals at an early stage of infection and providing for their health care and follow-up can provide important epidemiological and treatment information and strategies.

The Commission is impressed with the level of planning and implementation which has taken place at DoD and, in particular, its reliance on solid scientific and medical data as the basis for policy decisions.

Obstacle to Progress

- In 1986, DoD received $33.6 million for HIV research. By 1989, research funds for HIV will have declined to $8.8 million. This is detrimental to a sustained program and the external contract program will likely be cut back as a result.

RECOMMENDATIONS

11–43 Publication of data has lagged behind the HIV testing program. The Department of Defense should pursue expeditious peer-reviewed publication of this data so critical to public health and community leadership as they develop appropriately targeted education and prevention programs.

11–44 To maintain a complete research program, the Department of Defense will need sustained HIV-related funding of $20 million annually.

Section IV. Freedom of Movement

The Commission concurs with WHO that the screening of international travelers for HIV infection would require an unjustified, immense diversion of resources from other critical programs of education, protection of the blood supply, and care. At best, border screening programs would only briefly retard the spread of HIV.

RECOMMENDATIONS

11–45 The United States, through its relevant federal agencies, should communicate with other governments that may be considering institution of HIV-related travel restrictions in order to prevent the implementation of ineffective and cumbersome regulations.

11–46 The Centers for Disease Control annually produces and distributes a booklet, "Health Information for International Travel," which is sent to local health departments and individual physicians. Information on HIV infection should be expanded to increase understanding of HIV transmission and prevention, and include information on the relative safety of the blood supply in nations other than the United States and the avoidance of high-risk behaviors. These educational materials should discuss specific preventive measures in clear, easily understood language and should caution HIV-infected persons against travel to nations where other communicable diseases are endemic.

Section V. Refugees

Current United States policy requires testing of refugees for HIV and refusing asylum to HIV-infected refugees except in the most extraordinary circumstances. This policy is based on regulations issued by the United States Public Health Service under the authority of the Immigration and Nationality Act and the Public Health Service Act. These regulations were revised most recently in 1987 pursuant to Public Law 100-71, which required the addition of HIV infection to the list of "dangerous contagious diseases" warranting exclusion. Medical and other professionals testifying before the Commission have questioned the medical and organizational basis of the regulations. As of April, four months into the program, six prospective refugees have been detected with HIV.

RECOMMENDATION

11–47 The Department of State, the Department of Health and Human Services, and the Immigration and Naturalization Service should reevaluate the policy of testing refugees 12 months after the implementation of this policy. This evaluation should include consideration of the change in level of protection offered to the United States by this policy, consideration of potential impact on refugee populations and host governments, and consideration of cost and benefits. Recommendations resulting from this reevaluation should be made to the President.

CHAPTER TWELVE: GUIDANCE FOR THE FUTURE

The Federal Response to the HIV Epidemic to Date

In June 1987, the President wisely directed that a comprehensive national strategy be developed over the ensuing year to deal with the HIV epidemic. He appointed a 13-member Commission on the HIV epidemic to accomplish this objective and provided them discrete guidance in the form of an Executive Order to chart their course. The preceding chapters in this report constitute the Commission's recommended national strategy. Until now, federal agencies have had to work as diligently as possible within existing frameworks and without reference to an integrated national plan.

Over the past year, the Commission has heard testimony from over 100 officials of the federal government representing virtually every agency which has been significantly involved in responding to the epidemic. In addition, Commission staff has met with congressional offices and reviewed voluminous documents which describe policies, programs and legislative initiatives designed to respond to the HIV epidemic. Hundreds of others, including persons infected with HIV, representatives of state and local governments, the private sector and community-based organizations have offered the Commission their reflections about what the response of the federal government has been and what the response should be.

Additionally, no comprehensive legislation addressing the HIV epidemic has been enacted by the Congress. While appropriations for HIV-related research and activities have steadily increased since 1982, no comprehensive substantive legislation has emerged. Congress has spent considerable time examining the HIV epidemic via committee hearings in both the House and Senate and in floor debate when various provisions were addressed. Several pieces of comprehensive HIV legislation have been introduced and considered, but none has yet been endorsed by both houses.

As a result of the aforementioned, all Commissioners believe we have now arrived at a key milestone for placing this epidemic under closer management control than heretofore practicable. With a national strategy in hand, Commissioners believe that some special management oversight entity is needed at this early juncture in the epidemic to see that an action plan to carry out the strategy is aggressively followed. The goal of this entity should be to help bring the existing institutional process up to an acceptable level of efficiency in the near term and to remain in being until demonstrated management control over the epidemic is assured.

Future Management Options

The Commission heard about and considered a number of possible recommendations regarding how the nation's response to the epidemic should be managed from this point onward. Some of these options came from witnesses and some were developed by Commissioners after listening to the many concerns and ideas expressed. These options include:

- Establishment of a national advisory commission on AIDS and HIV infection.
- Appointment of a Deputy Secretary for HIV and an oversight commission.
- Establishment of a separate Department of Health.
- Appointment of a Crisis Deputy Secretary within the new Department of Health.
- Establishment of a commission, Congressional AIDS committees, and a Cabinet-level AIDS officer.

- An Executive Order to put into effect the 20 most important recommendations made by this Commission.
- Revision and implementation of the Public Health Emergencies Provision of the Public Health Service Act to allow streamlined action when a public health emergency is declared.

RECOMMENDATIONS

12-1 In order to assure rapid implementation of the key recommendations of this report, the President should:

- Appoint a continuing external oversight committee, composed of seven members including experts on HIV infection and public members, to provide an ongoing evaluation of the nation's response to the epidemic.
- Clearly establish the chain of command from the Cabinet to all affected units of the federal government, with a single designated official to manage implementation of this report and related activities within the existing structure.

12-2 For the longer term, the President should assure that the following changes in federal health structure are evaluated:

- Establishment of an independent Department of Health because health care is now taking almost 12 percent of our national resources and may not be receiving appropriate attention or visibility within the current structure.
- An expansion of the Public Health Emergencies provision of the Public Health Service Act to enhance the ability of the nation's chief health officials to request the President to declare public health emergencies in the nation when public health information about such an event is made available by relevant federal, state, or local public health agencies, or other appropriate sources.
- Delegation of authority during a declared public health emergency to facilitate procedures which enhance emergency responsiveness including approaches to hiring, acquisition of new space, increases in personnel ceilings, awarding of grants and contracts, regulatory review, and interdepartmental and interagency activities.

APPENDICES

Appendix A

A HISTORY OF THE UNITED STATES' RESPONSE TO EPIDEMICS

Up to 1776

Smallpox was the most devastating disease of colonial times. Introduced from Europe, the disease quickly killed an estimated 50 percent of the entire native American Indian population -- nearly six million people. It was able to run through this population largely unchecked because the native population did not have the natural immunity of the Europeans who had lived with the disease for several centuries.

But the colonists, too, suffered from numerous outbreaks. From 1675 to 1775, there were only two intervals as long as five years when the colonies were entirely free of smallpox. New England had major epidemics in 1633, 1648, and 1666; New York in 1663; Virginia in 1667. (This last outbreak is thought to be responsible for the move of the Virginia capital away from Jamestown).

The foci of the epidemics were the great port cities -- New York City, Boston, New Orleans. The first public health measure tried against smallpox seems to have been the quarantine of incoming ships. New England, for example, established quarantine procedures in 1699 in response to their smallpox epidemics.

The first preventive medical measure for smallpox was variolation -- inoculation with smallpox matter taken from the lesions of a person with an active case of the disease. This procedure was introduced from Europe to the colonies by the Reverend Cotton Mather and Zabdiel Boylston during a smallpox epidemic in Boston in 1721. Results were clear and were confirmed in 1752 in another epidemic in Boston in which the mortality of those who had been inoculated was 1.5 percent versus an at-large mortality of 9.1 percent.

Yellow fever was another terrible disease in colonial America. There were approximately 135 major yellow fever epidemics from 1660 to the end of the nineteenth century. These epidemics, too, were concentrated largely in the port cities. (It is thought that yellow fever was brought to the colonies by mosquitoes aboard ships engaged in the Africa trade). In this period, Philadelphia suffered 20 epidemics, New York City 15, Boston 8, and Baltimore 7. Boston, Philadelphia, and Charleston were all struck in the 1690's. In Charleston, seven percent of the population died in two months in 1699. Medical treatment for this disease was the normal seventeenth and eighteenth century method for treating any fever -- bloodletting and purging. No public health measures seem to have been directed at control of the disease. At this point, there was still no idea of the cause -- whether it was contagious or caused by "miasma," that is, pollution in the air.

Two other diseases of note in these times were typhoid fever and diphtheria. In 1730, typhoid fever epidemics broke out in Connecticut and South Carolina and the disease rapidly spread throughout the colonies. It was estimated that approximately 500,000 persons were infected every year, of whom 30,000 to 40,000 died annually.

Diphtheria was the other colonial disease which caused great mortality. One of the first modern outbreaks of epidemic diphtheria occurred in New England in 1735. This episode killed 5,000 persons overall or 2.5 percent of the total New England population. The vast majority of its victims were children. At this time, there was no effective medical procedure to cure or alleviate symptoms. Death was usually from suffocation as the false membrane completely closed off the throat. Diphtheria is a highly contagious disease and quarantine was and still is a common and effective public health procedure for this disease.

Up to the Twentieth Century

At the time of the American Revolution, the average life expectancy of the American citizen was less than 40 years of age. Smallpox was still the greatest problem -- responsible for 10 percent of all deaths and the single greatest cause of infant mortality. But this communicable disease was one of the first to disappear as a threat.

It was in 1798 that Edward Jenner announced his discovery that inoculation with cowpox protected the recipient from smallpox. This represented a great advance over variolation. People could no longer contract and spread the disease as sometimes occurred when it was acquired through inoculation with the live smallpox virus.

The disappearance was brought about through one method -- preventive inoculation, either variolation or vaccination. These preventive measures were actively espoused by two American Presidents. In 1776, Washington ordered the entire Continental Army variolated and, in 1800, Jefferson vaccinated himself, his family, and his friends while generally encouraging the practice.

The effectiveness of vaccination was firmly established in 1802 by a series of controlled experiments on human volunteers. These were the first controlled medical experiments on humans in the United States -- the first clinical trials. The incidence of the disease gradually tapered off, with the last reported case of smallpox in the United States occurring in 1953.

But while smallpox was beginning to disappear from the American landscape, yellow fever was beginning to loom larger. In the 1790's, major epidemics of yellow fever struck Charleston, Baltimore, and New Orleans. The largest epidemic, however, struck Philadelphia in 1793. By the time this outbreak ended, 5,000 people had died. As a direct response to this epidemic, the city created its Board of Health in 1793.

While there was still no adequate medical treatment for yellow fever, two differing public health approaches were followed. Those who believed in the growing "germ theory" of disease advocated quarantine and isolation for the ill. Those who felt that the condition was caused by "miasma" began massive public works efforts. These included waste removal and improvement of the water purification processes. Much of the infrastructure of cities -- sewage treatment and water purification plants -- came into existence as a result of attempts to control epidemic diseases.

These public works also helped control another disease problem -- the spread of cholera. This disease first became a problem in 1832 when the entire country was struck by an epidemic that had raged worldwide for six years and was brought to the United States by Irish immigrants. In New York City, the epidemic lasted about six weeks and 3,000 people perished. The city of New Orleans was hardest hit with 5,000 deaths, roughly 20 percent of its population.

The next virulent cholera epidemic struck 16 years later in 1848. In New York City 20,000 contracted the disease and of these 8,000 died. New Orleans again lost 5,000 citizens and the disease spread up the Mississippi Valley and went west with the forty-niners. Cholera epidemics recurred in 1853, 1866, and 1873.

Public health measures directed at control of the spread of this disease were confused by the "germ theory" and "miasma theory" controversy. Health officers generally supported both quarantine and sanitary measures.

Yellow fever epidemics continued to occur with alarming frequency for the next hundred years. An epidemic in New York City in 1798 killed 1,600. It was followed by two more in 1805 and 1822. The disease peaked in the 1850's while continuing to strike mostly port cities. New Orleans was again most affected -- in four outbreaks in the decade the city lost almost 20,000 people.

A severe outbreak which killed 15,000 persons occurred 30 years later in the Mississippi Valley and prompted the first national public health action. Up to this time, (1878) involvement of the federal government in health issues had been mostly limited to two actions taken in 1798. At that time, Congress set up a system of compulsory hospital insurance for merchant seamen and President Adams established "marine hospitals" to provide care for sick and disabled merchant seamen. The federal government later centralized direction of the marine hospitals under the Surgeon General of the Marine Hospital Service in 1871.

In 1878, Congress passed the National Quarantine Act which gave some quarantine power to the Surgeon General of the Marine Hospital Service. It allowed the Surgeon General to declare quarantine, but allowed local authority to overturn any such decision. No appropriations were made available for the implementation of this Act.

It was also partly in response to this same yellow fever epidemic that the National Board of Health was established by the Congress in the following year. This body accomplished little and was terminated four years later under pressure from the Surgeon General.

The federal government increased its role in the control of epidemic disease by giving the Marine Hospital Service a yearly appropriation of $100,000 to provide assistance to the states in preventing communicable disease epidemics and also by establishing the Hygienic Laboratory on Staten Island. This laboratory originally carried out examinations of specimens from immigrants entering the country. It soon began investigation into the causes of disease and other independent research. Four years later, it was transferred to Washington, D.C. and it became the National Institute of Health in the 1930's.

Prior to these actions, public health had been the province solely of state and local governments and the affected citizens themselves. The first governmental health actions taken were by state and local health boards, most of which had been established in response to previous outbreaks of communicable disease. Thus, in 1855 when New Orleans was being struck by epidemics of yellow fever and cholera, Louisiana created the first state board of health. The Metropolitan Board of Health was created in New York City in 1866 during the third great cholera epidemic. Still, by 1872, only three states and the District of Columbia had established state boards of health.

The other diseases of colonial times were still afflicting the country. Typhoid fever, for example, killed more soldiers during the Civil War than died in battle. Diphtheria and tuberculosis were major problems as well.

Diphtheria swept across Europe and the United States in 1857 and became endemic in many large cities. In New York, the average mortality rate for this disease for a period of six years never fell below 42 percent. From 1866 to 1890, diphtheria caused 43,000 deaths in New York City. In 1885, John O'Dwyer pioneered the technique of intubation (insertion of a tube into the trachea) which greatly decreased case fatality rates. In 1892, the New York Department of Health established a bacteriological laboratory and this laboratory demonstrated that half of all diphtheria cases in the city were "pseudo-diphtheria." This meant that quarantine of suspected diphtheria cases was actually causing more cases to occur. Patients who did not really have the disease were being put in the same ward with actual cases and becoming ill from the exposure. This discovery naturally reduced the number of cases. Diphtheria was finally dismissed as a serious threat when Emile Roux developed an antitoxin in 1893. Diphtheria antitoxin was first used to combat an epidemic in Massachusetts in 1900. The New York City Department of Health began the first program of active immunization of school children in the United States for diphtheria in 1927. Since that time, the number of cases has decreased in the United States to the rate of four per year.

Tuberculosis was a disease that had been endemic in the United States for many years. With Dr. Robert Koch's demonstration in 1882 that the disease was caused by a bacillus and the realization that the disease was preventable and not genetic as previously thought, efforts were made to stamp out the disease. In 1884, the first tuberculosis sanatorium for the poor was established in New York. In 1889, the New York City Department of Health, declaring that tuberculosis was "communicable and preventable," developed public health policy which was implemented in 1893 and 1894. These policies required that public institutions report all cases of tuberculosis to the Department of Health. Physicians were encouraged with the incentive of free diagnostic services to report voluntarily. When this voluntary program failed, the requirements were made mandatory. At the same time, in 1892, the Pennsylvania Society for the Prevention of Tuberculosis was founded. This body represented the first effort by both lay and professional people to attack a specific disease.

It was at the end of the century that schools first became involved in health issues. In 1894, Boston became the first city to employ school medical inspectors to identify and send home the contagiously ill. The next year, New York state appointed a chief medical inspector for the state's schools. But these school health services lost their medical emphasis as authority was transferred from local boards of health to boards of education. By 1911, three out of every four cities vested health authority in boards of education.

Up to the Present

The turn of the century, for all the advances made in the health field, ended on an ominous note. In 1899 there was an outbreak of the bubonic plague in New York City. Another outbreak occurred in San Francisco two years later. Both of these were controlled by public health measures still used today to control the plague -- quarantine and sanitation.

More ominous events had occurred in 1894 when Vermont reported 132 cases of polio in one year -- the largest number of poliomyelitis cases to date anywhere in the world. The death rate from this disease was 13.5 percent. Five years before this, the first major episode of influenza had struck the United States. After this initial bout, epidemics of varying degrees of severity began to strike the United States regularly. Epidemics of influenza A still occur every one to three years in this country, and influenza B every three to four years.

But more medical advances did occur. In 1900, Major Walter Reed identified the mosquito as the vector for yellow fever. This meant that the disease, while transmissible, was not contagious. It eliminated several inappropriate public health strategies, most notably isolation and quarantine, and it pointed to correct ones. These correct methods, which were essentially ways of reducing the mosquitoes' breeding habitat, were so effective that within 20 years of Walter Reed's discovery, yellow fever had been eliminated from the United States. The last epidemic of yellow fever struck New Orleans in 1905, causing 3,500 cases and 400 deaths. After this, New Orleans moved to eliminate mosquito breeding grounds and no further epidemics occurred.

Medical research was progressing rapidly at this time as well. In 1910, Dr. Paul Erlich discovered salvarsan (better known as "606" and so named because it was the 606th compound he tested for effectiveness in treating the disease) for use against syphilis. This was the first chemotherapeutic agent ever developed, but this "magic bullet" was only partially effective. Its discovery, however, stimulated further research which led eventually to the development of the sulfonamides and antibiotics.

In the 1930s and 1940s, before the advent of antibiotics, the number of deaths from syphilis in the United States averaged from 15,000 to 20,000 per year. In 1941, gonorrhea and syphilis were the second and third most reported communicable diseases in America (behind measles). After the steep decline in the number of cases following the introduction of penicillin and the other antibiotics, the number of cases has been steadily rising. The number of cases of all stages of syphilis has quadrupled since 1957.

Syphilis has been one of the major endemic diseases in this country since the 16th century. However, it was with the country going to war in 1914 that many of the first efforts to reduce incidence of the disease were pursued in the name of public health. The most striking of these was the attempt to close all the red light districts near any military base, but other measures included isolation and quarantine. The stigmatization which sometimes accompanied diagnosis created great difficulty in the public health arena for establishing public policy regarding the control of this disease. Another of the most commonly cited reasons for the failure to control the disease is that sex education was not a permissible public health measure in the country at that time.

It was also at the turn of the century that federal involvement became greater. In 1902, the Marine Hospital Service was expanded in the first step of its transition into the Public Health Service (PHS) and was renamed the United States Public Health and Marine Hospital Service.

In 1909, the Public Health and Marine Hospital Service (PHMHS) published Bulletin 56 which showed that between 1880 and 1907, 500 outbreaks of milk-borne disease had occurred. The Board of Health of New York City made pasteurization of milk mandatory. PHS, in 1924, issued its first Standard Milk Ordinance and Code in order to ensure uniform standards across the country.

Also in 1909, the Surgeon General decided that PHMHS should play a more active role in the conquest of typhoid fever. PHMHS paid special attention to water-borne typhoid because of its prevalence and the ease with which it could be corrected. PHMHS was also very involved in setting up local health organizations. In the previous century, they had encouraged local community efforts by building marine hospitals. Now, it was because of a recommendation from PHMHS that the first county health organization was established after a typhoid fever outbreak in Yakima County, Washington.

The Public Health Service, so named in 1912, was made responsible for the care of disabled war veterans in 1918. PHS rapidly expanded until in 1922 when it had 81 hospitals operating across the country. But in 1924 the Veterans' Bureau -- the predecessor of the Veterans' Administration -- assumed responsibility for all veterans' affairs and 57 PHS hospitals were transferred to the Bureau.

Not all of the federal involvement in health affairs came from the Public Health Service however. A national program to eliminate bovine tuberculosis was instituted in 1917 under the United States Department of Agriculture. This program included elimination of all infected cattle and the pasteurization of milk. It was instrumental in ending the threat of this form of the disease.

Private citizens were also involved in health issues. In 1918, 23 state and local associations joined together to form the National Tuberculosis Association. (This became the American Lung Association in 1973). With the discovery of streptomycin which accelerated the decline in the incidence and mortality from tuberculosis, this disease gradually became less of a threat.

Influenza, which had been making its periodic recurrences since the end of the previous century, suddenly became a focus of attention. In 1918 and 1919, an influenza pandemic killed 20 million people worldwide and 548,000 in the United States alone. All public health measures were ineffective, including the closing of public establishments and the wearing of face masks. Other major epidemics of the disease have occurred in 1947, 1957, and 1968.

Just before the great influenza epidemic, the northeastern part of the United States was struck by a devastating poliomyelitis epidemic. In New York City alone, 9,000 cases occurred. Cases occurred throughout the summer months in the 1930's. This led, in 1938, to the establishment of the National Foundation for Infantile Paralysis, a private philanthropic effort which funded research into cures and therapy for the disease. This organization funded the first fund-raising campaign of its kind, the March of Dimes. Polio outbreaks continued throughout the 1940's. The breakthrough for control of this disease came in 1953 when Dr. Jonas Salk developed his inactivated polio vaccine. The availability of a cure stimulated federal involvement in the production and distribution of vaccine and firmly established the federal government as the leader in the health field.

The Public Health Service remains the principal health agency of the federal government. The mission of PHS is to protect, improve, and advance the health of the American people. In that regard, PHS plays an active role in responding to various health crises, including epidemics of communicable disease.

CHRONOLOGY

1633 1648 1666	Smallpox epidemics in New England.
1663	Smallpox epidemic in New York.
1667	Smallpox epidemic in Virginia.
1668-1893	Yellow fever. There were 135 major yellow fever epidemics in American port cities through this time. There has been no outbreak of yellow fever in the United States since 1942. The case mortality for most of these epidemics varied between 12 percent and 80 percent.
1675-1775	There were only two five-year intervals when the colonies were entirely free of smallpox. The main centers of infection were port cities like Boston, New York, and Charleston.
1699	Yellow fever outbreak in Charleston killed seven percent of the population.
1721	Rev. Cotton Mather and Zabdiel Boylston began the use of variolation (smallpox inoculation) during a severe smallpox epidemic in Boston. It was highly effective.
1730	Typhoid fever epidemics occurred in Connecticut and South Carolina and spread throughout the colonies. Approximately 30,000 to 40,000 persons died of typhoid fever each year and approximately 500,000 were infected each year.
1735	One of the first modern outbreaks of epidemic diphtheria occurred in New England. It killed 5,000 people overall or 2.5 percent of the total population. The vast majority of these deaths occurred among children.
1752	Another epidemic of smallpox hit Boston. Variolation was clearly demonstrated to be effective -- a case fatality rate of 1.5 percent among those variolated versus 9.1 percent in the general population.
1776	At the time of the American Revolution, smallpox was the greatest cause of infant mortality and accounted for 10 percent of all deaths.
1776	George Washington ordered variolation for every man in the American Army.
1776	The average life expectancy of American citizens was less than 40 years.
1790's	Yellow fever epidemics ocurred in Charleston, Baltimore, and New Orleans.
1790's	Diptheria was epidemic. This disease is highly contagious and isolation was an effective measure commonly employed. Quarantine of adult contacts from food handling is also still employed.
1793	Yellow fever, Philadelphia. Public health measures in this epidemic turned on which theory of disease was ascribed to -- either contagious (in which case quarantine was recommended) or anti-contagious (in which case sanitary measures were pushed). 5,000 persons died in this epidemic.
1793	In direct response to the yellow fever epidemic, a Board of Health was created in Philadelphia.

1798	Edward Jenner announced that inoculation with cowpox protected the recipient from smallpox.
1798	Yellow fever, New York City, 1,600 died.
1798	Congress set up a system of compulsory hospital insurance for merchant seamen.
1798	President John Adams established "marine hospitals" to provide care for sick and disabled merchant seamen.
1802	A series of controlled experiments of human volunteers established the value of vaccination -- literally, inoculation with cowpox. This was the first controlled medical experiment on humans in the United States. Effective control of smallpox depends on one factor -- vaccination.
1805	Yellow fever, New York City.
1811	Congress authorized the establishment of a separate hospital service for naval personnel.
1822	Yellow fever, New York City.
1832	Cholera epidemic. In New York City, a quarantine was established against the advice of the professional medical community. Quarantine was ineffective because cholera cannot be contracted casually. In New York, the epidemic lasted about six weeks and 3,000 people perished. The city of New Orleans was hardest hit with 5,000 deaths -- 20 percent of the population.
1848	Cholera epidemic. In New York, 20,000 people were struck of whom 8,000 died. Almost 5,000 died in New Orleans. The disease spread up the Mississippi Valley and went west with the forty-niners.
1850's	Yellow fever reached its peak in the 1850's striking New Orleans hardest. In four outbreaks in this decade, New Orleans lost almost 20,000 people.
1853	Cholera epidemic.
1855	Louisiana created the first state board of health.
1857	Diphtheria swept Europe and America and became endemic in large cities. In New York, the average mortality rate for this disease for a period of six years never fell below 42 percent.
1861-1865	Typhoid fever killed more soldiers in the Civil War than died in battle.
1866	Cholera epidemic, relatively mild.
1866	The Metropolitan Board of Health was established in New York City.
1866-1890	Diphtheria caused 43,000 deaths in New York City.
1869	Massachusetts established the first effective state board of health.
1871	The federal government centralized direction of its marine hospitals under the Surgeon General of the Marine Hospital Service. This was located within the Treasury Department.
1872	Only three states and the District of Columbia had established boards of health.
1873	Cholera epidemic, widespread.
1874	The bacillus responsible for causing leprosy was identified. This altered the tradition of separating lepers out.
1878	Yellow fever, Mississippi Valley. More than 75,000 people were stricken and 15,000 died in this outbreak.
1878	It was this epidemic of yellow fever which prompted the passage of the National Quarantine Act which gave some quarantine power to the Surgeon General of the Marine Hospital Service. It allowed the Surgeon General to declare a quarantine, but allowed local authority to overturn the decision. There were no appropriations made available for implementing this Act.
1879	A National Board of Health was established by Congress. This body did little and was terminated four years later under pressure from the Surgeon General.
1882	Dr. Robert Koch, developer of Koch's postulates, demonstrated that tuberculosis was caused by a bacillus.
1883	National Board of Health was terminated.

1883	The Marine Hospital Service was given a yearly appropriation of $100,000 to provide assistance to states in preventing epidemic diseases.
1884	Edward L. Trudeau established the first tuberculosis sanatorium for the poor in the United States.
1885	John O'Dwyer pioneered the technique of intubation which greatly reduced the mortality rate for diphtheria.
1887	The Hygienic Laboratory was created on Staten Island. It originally carried out examinations of bacteriological specimens from immigrants to determine their eligibility for entering the country. The lab soon began investigation into the causes of disease and other independent research. It was transferred to Washington, D.C. four years later and became the National Institute of Health in the 1930's.
1889	The New York City Department of Health declared tuberculosis to be "communicable and preventable." Public health policy was developed which was implemented in 1893-1894. This was a great change from policy before isolation of the etiologic agent, when the disease was assumed to be hereditary and so chief concern was felt by the patient and family.
1889	Influenza pandemic. In the United States, epidemics of influenza A still occur every one to three years and epidemics of influenza B occur every three to four years.
1892	The New York City Department of Health established a bacteriological laboratory. This lab demonstrated that half of all diphtheria cases in the city were actually "pseudo-diphtheria." This meant that quarantine of suspected diphtheria cases was actually causing more cases to occur. Patients who did not really have the disease were being put in the same ward as actual cases and becoming ill from the exposure.
1892	The Pennsylvania Society for the Prevention of Tuberculosis was founded. This was the first effort by both lay and professional people to attack a single disease.
1893	Diphtheria antitoxin was developed in Paris by Emile Roux.
1893	New York City required that public institutions report all cases of tuberculosis. Physicians were encouraged to report voluntarily with the incentive of free diagnostic services. Reporting requirements were made mandatory when the voluntary program failed.
1894	Boston became the first city to employ school medical inspectors to identify and send home the contagiously ill.
1894	Vermont reported 132 cases of polio in one year—the largest epidemic to date anywhere in the world. The death rate was 13.5 percent.
1895	New York state appointed a chief medical inspector for the state's schools. These school health services lost their medical emphasis as authority was transferred from local boards of health to boards of education. By 1911, three out of four cities vested health authority in boards of education.
1899	Bubonic plague outbreak in New York City.
1900	Diphtheria was the ninth leading cause of deaths in the United States, responsible for 2.3 percent of all deaths.
1900	The first large scale use of diphtheria antitoxin was used to combat an epidemic in Massachusetts.
1900	Major Walter Reed identified the mosquito as the vector for yellow fever. This meant that the disease, while transmissible, was not contagious. It eliminated several public health strategies (e.g., isolation and quarantine) and pointed to the correct ones (e.g., protection from mosquito bites).
1901	Bubonic plague in San Francisco. The public health measures taken then are still those recommended by the United States Public Health Service (PHS) -- quarantine and sanitation measures.

1902	The Marine Health Service was expanded in the first step of its transition into PHS and was renamed the United States Public Health and Marine Hospital Service.
1902	New York City introduced nurses into schools.
1905	The last epidemic of yellow fever occurred in the United States. It struck New Orleans, causing 400 deaths and 3,500 cases. New Orleans moved to eliminate mosquito breeding grounds after this.
1907	Salversan, a cure for syphilis and the first "magic bullet" for any disease, was discovered.
1909	The Public Health Service published Bulletin 56 which showed that between 1880 and 1907, 500 outbreaks of milk-borne disease had occurred. The Board of Health of New York City made pasturization of milk mandatory.
1909	The Surgeon General of the United States Public Health and Marine Hospital Service (PHMHS) decided that PHMHS should play a more active role in the conquest of typhoid fever. PHMHS paid special attention to water-borne typhoid because of its prevalence and the ease with which it could be corrected. PHMHS branched into sanitary engineering and its studies led to improved municipal water systems and improved sewage treatment facilities.
1911	The first county health organization was established after a typhoid fever outbreak in Yakima County, Washington.
1912	The Marine Health Service was renamed the Public Health Service and its duties were expanded.
1916	The northeastern part of the United States was struck by a devastating poliomyelitis epidemic. In New York City alone there were 9,000 cases.
1917	A national program to eliminate bovine tuberculosis was instituted under the United States Department of Agriculture. This program included elimination of all infected cattle and the pasteurization of milk.
1918	Twenty-three state and local associations joined together to form the National Tuberculosis Association. This became the American Lung Association in 1973.
1918	The Public Health Service was made responsible for the care of disabled war veterans. PHS rapidly expanded until 1922, at which time it had 81 hospitals operating across the country.
1918–19	Influenza pandemic killed 20 million worldwide and 548,000 in the United States alone. All public health measures were ineffective, including the closing of public establishments and the wearing of face masks.
1921	Last typhus outbreak in the United States.
1921	A public hospital for the care of patients with leprosy was established in Carville, Louisiana.
1924	Clinical trials showed that diphtheria immunization was successful. Since this time, there has been a drastic decline in the number of cases, which has persisted to the present rate of less than four cases per year for the entire United States.
1924	The Veterans' Bureau -- the predecessor of the Veterans' Administration -- assumed responsibility for all veterans' affairs, and 57 PHS hospitals were transferred to the Bureau.
1924	PHS issued its first Standard Milk Ordinance and Code in order to ensure uniform standards across the country.
1928	The New York City Department of Health began the first program of active immunization of school children in the United States.
1938	The National Foundation for Infantile Paralysis, the sponsor of the March of Dimes, was established.
1940's	Polio outbreaks, generally in the summer.
1943	The discovery of streptomycin which accelerated the decline in the incidence and mortality of tuberculosis.
1947	Influenza pandemic.

1953	Dr. Jonas Salk developed inactivated polio vaccine.
1950's	Polio outbreaks stimulated federal involvement in the production and distribution of vaccine.
1953	Last reported case of smallpox in the United States.
1957	Influenza pandemic.
1968	Influenza pandemic.
1981	The United States Public Health Service hospitals were closed.

Appendix B

BUDGET ESTIMATES FOR FINAL REPORT RECOMMENDATIONS

(In millions)

	Total Federal dollars over FY 88 appropriated	Total State	Total
Prevention and education	200	100	300
Incidence and prevalence	50		50
Drug abuse	924.5	750	1,674.5
International	25		25
Finance	200	200	400
Patient care	247.5	52.5	300
Research	300		300
Societal	50.5		50.5
Total	1,997.5	1,102.5	3,100

These are the estimated low end (start-up funding) cost estimates for the recommendations.

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Appendix C

WALTER REED HIV-1 STAGING CRITERIA

Introduction

The purpose of this staging criteria is to provide physicians with a pragmatic HIV-1 diagnostic system. This system is based upon qualitative and quantitative clinical parameters and could be used to classify and follow patients throughout the entire course of their infection. The system is based on the following staging parameters:

A. Exposure to HIV-1
B. Presence of HIV-1 antibody
C. Chronic lymph node swelling
D. Number of T-helper cells
E. Presence of Delayed Hypersensitivity Reaction (DHS)
F. Candida fungal infection
G. Other opportunistic infections

Walter Reed Staging Criteria (WR)

WR0: High-risk contacts of HIV-1 infected individuals or blood products. These individuals have negative antibody tests and all other staging parameters are within normal limits.

WR1: Individuals are only HIV-1 antibody positive and all other staging parameters are within normal limits.

WR2: Individuals are HIV-1 antibody positive, exhibit chronic lymph node swelling, but all other staging parameters are within normal limits.

WR3: Individuals are HIV-1 antibody positive, chronic lymph node swelling may be present, but T-helper cell counts are below normal. All other staging parameters are within normal limits.

WR4: Individuals have HIV-1 antibody, chronic lymph node swelling may be present, T-helper cell counts are below normal, partial impairment of the Delayed Hypersensitivity Reaction (DHS). All other staging parameters are normal.

WR5: Individuals have HIV-1 antibody, chronic lymph node swelling may be present, T-helper cell counts below normal, DHS practically or completely absent, candida fungal infection may be present, but other opportunistic infections are absent.

WR6: Individuals have HIV-1 antibody, chronic lymph node swelling may be present, T-helper cell counts below normal, DHS practically or completely absent, candida fungal infections may be present and other opportunistic infections are present.

A STAGING SYSTEM FOR HTLV-III DISEASE

STAGE	HTLV-III ANTIBODY AND/OR VIRUS ISOLATION	CHRONIC LYMPHADENOPATHY	T-HELPER CELLS/mm^3	DHS	THRUSH	O.I.
WR 0	—	—	>400	NL	—	—
WR 1	+	—	>400	NL	—	—
WR 2	+	+	>400	NL	—	—
WR 3	+	±	<400	NL	—	—
WR 4	+	±	<400	P	—	—
WR 5	+	±	—	C AND/OR +		—
WR 6	+	±	—	PC	±	+

The Walter Reed staging classification for HTLV-III/LAV infection. The essential criteria for assignment to each stage are indicated by hexagons. DHS denotes delayed hypersensitivity; NL, normal, P, partial cutaneous anergy, which is defined as an intact cutaneous response to only one of the four test antigens; C, complete cutaneous anergy to the four test antigens; and O.I., opportunistic infection.

Appendix D

OFFICE OF PERSONNEL MANAGEMENT

Guidelines for AIDS Information and Education and for Personnel Management Issues

March 1988

Introduction

This information and guidance is designed to assist Federal agencies in establishing effective AIDS education programs and in fairly and effectively handling AIDS-related personnel situations in the workplace. In this guidance, the term AIDS is used to refer either to the general AIDS phenomenon or to clinically diagnosed AIDS as a medical condition. HIV (human immunodeficiency virus) is used when the discussion is referring to the range of medical conditions which HIV-infected persons might have (i.e., immunological and/or neurological impairment in early HIV infection to clinically diagnosed AIDS).

General Policy

Guidelines issued by the Public Health Service's Centers for Disease Control (CDC) dealing with AIDS in the workplace state that "the kind of nonsexual person-to-person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of [AIDS]." Therefore, HIV-infected employees should be allowed to continue working as long as they are able to maintain acceptable performance and do not pose a safety or health threat to themselves or others in the workplace. If performance or safety problems arise, agencies are encouraged to address them by applying existing Federal and agency personnel policies and practices.

HIV infection can result in medical conditions which impair the employee's health and ability to perform safely and effectively. In these cases, agencies should treat HIV-infected employees in the same manner as employees who suffer from other serious illnesses. This means, for example, that employees may be granted sick leave or leave without pay when they are incapable of performing their duties or when they have medical appointments. In this regard, agencies are encouraged to consider accommodation of employees' AIDS-related conditions in the same manner as they would other medical conditions which warrant such consideration.

Also, there is no medical basis for employees refusing to work with such fellow employees or agency clients who are HIV-infected. Nevertheless, the concerns of these employees should be taken seriously and should be addressed with appropriate information and counseling. In addition, employees, such as health care personnel, who may come into direct contact with the body fluids of persons having the AIDS virus, should be provided appropriate information and equipment to minimize the risks of such contact.

OPM encourages agencies to consider the following guidelines when establishing AIDS education programs and in carrying out their personnel management responsibilities.

I. *AIDS INFORMATION AND EDUCATION PROGRAMS*

There are several important considerations in establishing effective AIDS information and education programs. The following guidance is intended to help agencies develop methods for establishing successful programs.

A. *Timing and Scope of AIDS Information and Education Efforts*

AIDS information and education programs are most effective if they begin before a problem situation arises relative to AIDS and employee concerns. Experience in the private sector has demonstrated that employees' level of receptivity to accurate information will be higher when management has a policy of open communications and when educational efforts are initiated before a problem situation occurs. Education and information should be of an ongoing nature. This approach will reassure employees of management's commitment to open communications and employees will receive updated information about AIDS. By providing AIDS information to all employees, agencies will enhance employees' understanding about the nature and transmission of the disease.

B. *Educational Vehicles*

Education and information efforts may be carried out in a variety of ways. Agency news bulletins, personnel management directives, meetings with employees, expert speakers and counselors, question and answer sessions, films and video-tapes, employee newsletters, union publications, factsheets, pamphlets, and brochures are likely to be effective means of providing information to employees about AIDS.

C. *Employee Assistance Programs*

For employees who have personal concerns about AIDS, agency employee assistance programs (EAPs) can be an excellent source of information and counseling, and can provide referrals, as requested, to community testing, treatment, and other resources. EAPs can also provide counseling to employees who have apprehensions regarding the communicability of the disease or other related concerns. Because EAPs are in a unique position to offer information and assistance, agencies are encouraged to establish AIDS information, counseling, and referral capabilities in their EAPs and to make employees and supervisors aware of available services. In addition, EAPs can be a good source of managerial/supervisory training on AIDS in the workplace. As with other services provided by the EAP, strict adherence to applicable privacy and confidentiality requirements must be observed when advising employees with AIDS-related concerns. In addition to services provided by the EAP, the agency's occupational health program, health unit, or medical staff should be prepared to assist employees seeking information and counseling on AIDS.

D. *Training and Guidance for Managers and Supervisors*

Supervisors and managers should be prepared to deal with employee concerns and other issues related to AIDS in the workplace. Agencies should consider, therefore, conducting ongoing training and education programs on AIDS for their managers and supervisors on the medical and personnel management dimensions of AIDS. These programs can be used to educate managers and supervisors on the latest research on AIDS in the workplace, to provide advice on how to recognize and handle situations which arise in their organizations, and to convey the importance of maintaining the confidentiality of any medical and other information about employees' health status. In addition, managers and supervisors should be given a point of contact within the agency where they can call to obtain further information or to discuss situations which arise in their work units. Agencies should attempt to initiate training and guidance activities before problems occur.

E. *Sources of Information and Educational Materials*

A great deal of information about AIDS is available to Federal agencies. OPM encourages agencies to explore various sources of information and to keep abreast of the latest research on AIDS in the workplace. The U.S. Public Health Service (PHS) has developed a great deal of material on the medical and other aspects of AIDS. Information about AIDS can be obtained by requesting it from PHS offices or from the AIDS Clearinghouse (America Responds to AIDS, P.O. Box 6003, Rockville, Maryland 20850; telephone (800) 342-7514). PHS offices are located throughout the country and can be contacted for information relating to AIDS. (See section III for a listing of PHS regional office locations). In addition, the American Red Cross has developed an extensive assortment of educational materials on AIDS. Information about the materials available through PHS and other sources is contained in section III. [For reasons of space, section III which lists AIDS information sources and the location of PHS regional offices is not included in this report.]

II. *PERSONNEL MANAGEMENT ISSUES AND CONSIDERATIONS*

When AIDS becomes a matter of concern in the workplace, a variety of personnel issues may arise. Basically, these issues should be addressed within the framework of existing procedures, guidance, statutes, case law, and regulation. Following is a brief discussion of AIDS-related issues which could arise in various personnel management areas, along with some basic guidance on how to approach and resolve such issues. Agencies are cautioned that, as with any complex personnel management matter, the resolution of a specific problem must be based on a thorough assessment of that problem and how it is affected by contemporary information and guidance about AIDS, current law and regulation bearing on the involved issue, and the agency's own policies and needs.

A. *Employees' Ability to Work*

An HIV-infected employee may develop a variety of medical conditions. These conditions can range all the way from immunological and/or neurological impairment in early stages of HIV infection to clinically diagnosed AIDS. At some point, a concern may arise whether such an employee, given his or her medical condition, can perform the duties of the position in a safe and reliable manner. This concern will typically arise at a point when the HIV-infected employee suffers health problems which affect his or her ability to report for duty or perform. Also, in some situations the concern may stem from the results of a medical examination required by the employee's position. Under OPM's regulations in 5 C.F.R. Part 339, Medical Determination Related to Employability, it is primarily the employee's responsibility to produce medical documentation regarding the extent to which a medical condition is affecting availability for duty or job performance. However, when the employee does not produce sufficient documentation to allow agency management to make an informed decision about the extent of the employee's capabilities, the agency may offer, and in some cases order, the employee to undergo a medical examination. Accurate and timely medical information will allow the agency to consider alternatives to keeping the employee in his or her position if there are serious questions about safe and reliable performance. It will also help determine whether the HIV-infected employee's medical condition is sufficiently disabling to entitle the employee to be considered for reasonable accommodation under the Rehabilitation Act of 1973 (29 U.S.C. Section 794).

B. *Privacy and Confidentiality*

Because of the nature of the disease, HIV-infected employees will have understandable concerns over confidentiality and privacy in connection with medical documentation and other information relating to their condition. Agencies should be aware that any medical documentation submitted to an agency for the purposes of an employment decision and made part of the file pertaining to that decision becomes a "record" covered by the Privacy Act. The Privacy Act generally forbids agencies to disclose a record which the Act covers without the consent of the subject of the record. However, these records are available to agency officials who have a need to know the information for an appropriate management purpose. Officials who have access to such information are required to maintain the confidentiality of that information. In addition, supervisors, managers, and others included in making and implementing personnel management decisions involving employees with AIDS should strictly observe applicable privacy and confidentiality requirements.

C. *Leave Administration*

HIV-infected employees may request sick or annual leave or leave without pay to pursue medical care or to recuperate from the ill effects of his or her medical condition. In these situations the agency should make its determination on whether to grant leave in the same manner as it would for other employees with medical conditions.

D. *Changes in Work Assignment*

Agencies considering changes such as job restructuring, detail, reassignment, or flexible scheduling for HIV-infected employees should do so in the same manner as they would for other employees whose medical conditions affect the employee's ability to perform in a safe and reliable manner. In considering changes in work assignments, agencies should observe established policies governing qualification requirements, internal placement, and other staffing requirements.

E. *Employee Conduct*

There may be situations where fellow employees express reluctance or threaten refusal to work with HIV-infected employees. Such reluctance is often based on misinformation or lack of information about the transmission of HIV. There is, however, no known risk of transmission of HIV through normal workplace contacts, according to leading medical research. Nevertheless, OPM recognizes that the presence of such fears, if unaddressed in an appropriate and timely manner, can be disruptive to an organization. Usually an agency will be able to deal effectively with such situations through information, counseling, and other means. However, in situations where such measures do not solve the problem and where management determines that an employee's unwarranted threat or refusal to work with a HIV-infected employee is impeding or disrupting the organization's work, it should consider appropriate corrective or disciplinary action against the threatening or disruptive employee(s). In other situations, management may be faced with an HIV-infected employee who is having performance or conduct problems. Management should deal with these problems through appropriate counseling, remedial, and, if necessary, disciplinary measures. In pursuing appropriate action in these situations, management should be sensitive to the possible contribution of anxiety over the illness to work behavior and to the requirements of existing Federal and agency personnel policies, including any obligations the agency may have to consider reasonable accommodation of the HIV-infected employee.

F. *Insurance*

HIV-infected employees can continue their coverages under the Federal Employees Health Benefits (FEHB) Program and/or the Federal Employees' Group Life Insurance (FEGLI) Program in the same manner as other employees. Their continued participation in either or both of these programs would not be jeopardized solely because of their medical condition. The health benefits plans cannot exclude coverage for medically necessary health care services based on an individual's health status or a pre-existing condition. Similarly, the death benefits payable under the FEGLI Program are not cancelable solely because of the individual's current health status. However, any employee who is in a leave-without-pay (LWOP) status for 12 continuous months faces the statutory loss of FEHB and FEGLI coverage but has the privilege of conversion to a private policy without having to undergo a physical examination. Employees who are seeking to cancel previous declinations and/or obtain *additional* levels of FEGLI coverage must prove to the satisfaction of the Office of Federal Employees' Group Life Insurance that they are in reasonably good health. Any employee exhibiting symptoms of any serious and life-threatening illness would necessarily be denied the request for additional coverage.

G. *Disability Retirement*

HIV-infected employees may be eligible for disability retirement if their medical condition warrants and if they have the requisite years of Federal service to qualify. OPM considers applications for disability retirement from employees with AIDS in the same manner as for other employees, focusing on the extent of the employee's incapacitation and ability to perform his or her assigned duties. OPM makes every effort to expedite any applications where the employee's illness is in an advanced stage and is life threatening.

H. *Labor-Management Relations*

AIDS in the workplace may be an appropriate area for cooperative labor-management activities, particularly with respect to providing employees education and information and alleviating AIDS-related problems that may emerge in the workplace. In addition, to the extent that an agency proposes AIDS-related policies or programs which would affect the working conditions of bargaining unit employees, unions must be accorded any rights they may have to bargain or be consulted as provided for under 5 U.S.C. Chapter 71.

I. *Health and Safety Standards*

In 1985, the CDC published guidelines relating to the prevention of HIV transmission in most workplace settings, *CDC Recommendations for Preventing Transmission of Infection with [HIV] in the Workplace,* 34 MMWR 681 (November 15, 1985). The CDC published specialized guidelines in 1987 relating to health-care workers (which in part updated the health-care worker provisions contained in the workplace guidelines), *CDC Recommendations for Prevention of HIV Transmission in Health-Care Settings,* 36 MMWR Supp. no. 2S (August 21, 1987). The Department of Health and Human Services (HHS) and the Occupational Safety and Health Administration (OSHA) of the Department of Labor have initiated a program to ensure compliance with safety and health guidelines and standards designed to protect health-care workers from blood-borne diseases, including AIDS. See Department of Labor/Department of Health and Human Services -- Joint Advisory Notice: *Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV),* 52 Fed. Reg. 41818 (October 30, 1987). The CDC and OSHA/HHS guidance is intended to increase the availability and use of educational information and personal protective equipment and to improve workplace practices bearing on the transmission of AIDS and other blood-borne diseases. OPM strongly encourages agencies, especially those with employees occupying health-care and related positions, to establish health and safety practices consistent with this guidance. Sources are available in OSHA to discuss the published guidelines.

J. *Blood Donations*

One area of personnel management which agencies may overlook when considering AIDS policies and practices is employee blood donations. OPM joins the American Red Cross in urging agencies to encourages employees to consider donating blood. Under guidelines established by the American Red Cross, there is no risk of contracting AIDS from giving blood. However, fears associated with AIDS have contributed to a situation where many of the nation's blood banks are in short supply. This situation threatens the health status of the American public.

As part of its effort to educate the public so as to overcome these fears, the American Red Cross has produced three publications which address blood donations where AIDS is an issue. These publications are: "You Can't Get AIDS From Giving Blood, But Fear Can Run Us Dry," "What You Must Know Before Giving Blood," and "AIDS and the Safety of the Nation's Blood Supply." These publications are available through your local Red Cross chapter or by contacting the Red Cross National Headquarters AIDS Public Education Program (by writing to 1730 "D" Street, N.W., Washington, D.C. 20006 or by calling (202) 639-3223).

Appendix E

PUBLIC HEARING SCHEDULE

Date	Subject	Site
1987		
September 1-2	Site Visit	New York City, NY
September 2-3	Site Visit	San Francisco, CA
September 9-10	Federal Overview	Washington, DC
September 30	Congressional Caucus	Washington, DC
October 15-16	State Response Hearing and Personnel Meeting	Washington, DC
November 10-12	Site Visit and Hearing	South Florida
November 24	Reports of the Institute of Medicine and the American Medical Association	Washington, DC
December 10-11	Incidence and Prevalence	Washington, DC
December 17-18	Intravenous Drug Abuse and HIV Infection	Washington, DC
1988		
January 13-15	Care	Washington, DC
February 18-20	Research: New Drugs, Vaccines, and Behavior	New York City, NY
February 29	Executive Session	Washington, DC
March 1-3	Prevention and Education	Washington, DC
March 16-18	Discrimination: Workplace, Housing, and Schools Ethics: Denial of Care and Research Testing: Confidentiality and Duty to Warn	Nashville, TN
March 24-25	Western States Response and Site Visits	San Francisco, CA
April 5-6	Societal and Legal Concerns	Washington, DC
April 18-20	International	Washington, DC
April 26-27	Finance	Washington, DC
May 9-11	Safety of the Blood Supply, AIDS in the Workplace, Health Care Worker Safety	Indianapolis, IN
May 16-18	Final Hearing	Washington, DC
June 7	Executive Session	Washington, DC
June 16-17	Executive Session	Washington, DC

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Appendix F

BIOGRAPHICAL INFORMATION

Presidential Commission on the Human Immunodeficiency Virus Epidemic

COLLEEN CONWAY-WELCH, of Tennessee. Since 1984, Dr. Conway-Welch has been a professor and the Dean of Nursing at Vanderbilt University and Associate Director of the Vanderbilt University Hospital Department of Nursing. She received her B.S.N. degree from the Georgetown University School of Nursing in 1965; her M.S.N. degree from the Catholic University of America in 1969; her C.N.M. degree from the Catholic Maternity Institute in 1969; and her Ph.D. degree from New York University in 1973. Dr. Conway-Welch was born April 26, 1944 in Iowa. She is married and resides in Nashville, Tennessee.

JOHN J. CREEDON, of Connecticut. Mr. Creedon has been with the Metropolitan Life Insurance Company in New York City since 1942. He has been serving as President of the Company since 1980, and Chief Executive Officer since 1983. Mr. Creedon is also Chairman of the Business Roundtable's Task Force on Health and Welfare Benefit Plans. He served as General Chairman of the Greater New York Blood Program Campaign for 1986 and 1987. Mr. Creedon earned his B.S. degree in 1952 from New York University School of Law, and his LL.B degree in 1955 and LL.M degree in 1962 from New York University School of Law. He served in the United States Navy during World War II. Mr. Creedon was born August 1, 1924 in New York City. He is married, has six children, and resides in New Canaan, Connecticut.

THERESA L. CRENSHAW, of California. Since 1975, Dr. Crenshaw has been the Director of the Crenshaw Clinic, which specializes in the evaluation and treatment of sexual dysfunction, sexual medicine, and human relationships. She was Immediate Past President of the American Association of Sex Educators, Counselors, and Therapists. Dr. Crenshaw received her B.A. degree from Stanford University in 1964 and her M.D. degree from the University of California at Irvine in 1969. She served in the United States Navy from 1967 through 1973. Dr. Crenshaw was born September 25, 1942 and resides in San Diego, California.

RICHARD M. DEVOS, of Michigan. Mr. DeVos co-founded Amway Corporation in 1959, and has since been serving as President of the Corporation. He attended Calvin College in Michigan. Mr. DeVos served in the United States Air Force from 1944 through 1946. He was born March 4, 1926. Mr. DeVos is married, has four children, and resides in Grand Rapids, Michigan.

KRISTINE M. GEBBIE, of Oregon. Since 1980, she has been an Adjunct Associate Professor with the Department of Psychiatric/Mental Health Nursing, School of Nursing at Oregon Health Science University. Prior to that, she was the Assistant Director for Health at the Department of Human Resources, and Administrator of the Oregon State Health Division in Portland. Mrs. Gebbie graduated from St. Olaf College (R.N., 1965) and the University of California School of Nursing (M.N., 1968). She was born June 26, 1943 in Sioux City, Iowa. Mrs. Gebbie is married, has three children, and resides in Portland, Oregon.

BURTON JAMES LEE III, of Connecticut. Since 1960, Dr. Lee has been a practicing physician at the Memorial Sloan-Kettering Cancer Center in New York, specializing in the diagnosis and treatment of lymphomas, and since 1981 has treated patients with

HIV infection. He was President of the General Medical Staff at the Memorial Sloan-Kettering Hospital from 1972 through 1974, and from 1983 through 1985. Dr. Lee earned his B.A. from Yale University in 1952 and his M.D. from the Columbia University College of Physicians and Surgeons in 1956. He was born March 28, 1930 in New York City. Dr. Lee is married, has three children and three step-children, and resides in Greenwich, Connecticut.

FRANK LILLY, of New York. Since 1976, Dr. Lilly has been Chairman of the Genetics Department of the Albert Einstein Medical Center in New York City. He has also served as a Professor of Genetics for the Albert Einstein College of Medicine since 1974. Dr. Lilly earned his B.S. degree from West Virginia University in 1951. He earned his first Ph.D. from the University of Paris in 1958, majoring in organic chemistry, and his second Ph.D. from the Cornell Graduate School of Medical Sciences in 1965, majoring in biology. Dr. Lilly served in the United States Army from January 1952 through December 1953. He was born August 28, 1930 in Charleston, West Virginia and resides in New York City.

JOHN CARDINAL O'CONNOR, of New York. John Cardinal O'Connor was ordained a priest in 1945. He was named Archbishop of New York in 1984, and Cardinal in 1985. John Cardinal O'Connor served as Bishop of Scranton, Pennsylvania in 1983. While in the United States Navy, 1952-1979, he was appointed Navy Chief of Chaplains in 1974, and Titular Bishop of Cursola and auxiliary to the Military Vicar in 1979. John Cardinal O'Connor was born January 15, 1920 in Philadelphia, Pennsylvania. He currently resides in New York City.

BENY J. PRIMM, of New York. Since 1983, Dr. Primm has been President of the Urban Resource Institute and, since 1969, President and Executive Director of The Addiction Research and Treatment Corporation in Brooklyn, New York. Dr. Primm graduated from West Virginia State College (B.S., 1950) and the University of Geneva (M.D., 1959). He served in the United States Army. Dr. Primm was born May 21, 1928 in Williamson, West Virginia. He has three children and resides in New Rochelle, New York.

PENNY PULLEN, of Illinois. Miss Pullen was first elected to the Illinois State House of Representatives in 1976, and has been serving in the State House since that time. In January 1987, she was appointed House Minority Leader. Miss Pullen is the sponsor of HIV-related legislation in the State of Illinois. She earned her B.A. degree from the University of Illinois at Chicago in 1969. Miss Pullen was born March 2, 1947, in Buffalo, New York. She currently resides in Park Ridge, Illinois.

CORY SERVAAS, of Indiana. Since 1973, Dr. SerVaas has been Editor and Publisher of The Saturday Evening Post. She has also served as President and Research Director of the Benjamin Franklin Literary and Medical Society and Medical Director of the Foundation for Preventative Medicine, 1976 to present. Dr. SerVaas earned her A.B. degree from the University of Iowa School of Journalism in 1946 and did post-graduate work at Columbia University. She earned her M.D. degree from the Indiana University School of Medicine in 1969. Dr. SerVaas was born June 21, 1924 in Pella, Iowa. She is married, has five children, and resides in Indianapolis, Indiana.

WILLIAM B. WALSH, of Maryland. Dr. Walsh founded Project HOPE (Health Opportunity for People Everywhere) in 1958, and has been serving as President and Medical Director since that time. He is also a clinical professor of internal medicine at Georgetown University. Dr. Walsh earned his B.S. degree in 1940 from St. John's University in New York, and his M.D. degree from Georgetown University School of Medicine in 1943. Dr. Walsh served in the United States Navy from 1941 to 1954. He received the Presidential Medal of Freedom in June 1987, and received the National Institute of Social Sciences Gold Medal in 1977. Dr. Walsh was born April 26, 1920 in Brooklyn, New York. He is married, has three sons, and resides in Bethesda, Maryland.

ADMIRAL JAMES D. WATKINS, (Chairman, Presidential Commission on the HIV Epidemic) U.S. Navy, Retired, of California. Admiral Watkins served as the Chief of

Naval Operations, U.S. Navy, from 1982 to 1986. Prior to this, he was Commander in Chief of the U.S. Pacific Fleet, from 1981 to 1982. Admiral Watkins is a 1949 graduate of the U.S. Naval Academy and received his master's degree from the Naval Postgraduate School in 1958. During his military service, Admiral Watkins received several Distinguished Service Medals, including three Legions of Merit and the Bronze Star. Admiral Watkins was born March 7, 1927 in Alhambra, California. He is married, has six children, and resides in the District of Columbia.

POLLY L. GAULT, (Executive Director, Presidential Commission on the HIV Epidemic). Prior to her appointment to the Commission, Ms. Gault served for six years as the Staff Director of the United States Senate Subcommittee on Education, Arts and Humanities chaired by Senator Robert T. Stafford of Vermont. For the previous four years, Ms. Gault managed the legislative activities of the Handicapped, Education and Aging Subcommittees of the Senate Labor and Human Resources Committee, as well as the Labor-HEW Appropriations Subcommittee for Senator Richard S. Schweiker of Pennsylvania, ranking Republican member. Ms. Gault was born in Abington, Pennsylvania, on June 15, 1953. She graduated from Mt. Holyoke College in 1975, Magna Cum Laude, Phi Beta Kappa.

Appendix G

PHYSICIAN REVIEW GROUP

Dr. James Baker is an Assistant Professor of Emergency Medicine at the Johns Hopkins University School of Medicine and is a member of the Johns Hopkins AIDS Research Group, and a member of the American College of Emergency Physicians Task Force on AIDS.

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Appendix H

EXECUTIVE ORDERS

Federal Register / Vol. 52, No. 124 / Monday, June 29, 1987 / Presidential Documents **24129**

Presidential Documents

Executive Order 12601 of June 24, 1987

Presidential Commission on the Human Immunodeficiency Virus Epidemic

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), and in order to create an advisory commission to investigate the spread of the human immunodeficiency virus (HIV) and the resultant acquired immune deficiency syndrome (AIDS) in the United States, it is hereby ordered as follows:

Section 1. *Establishment.* (a) There is established the Presidential Commission on the Human Immunodeficiency Virus Epidemic to investigate the spread of the HIV and the resultant AIDS. The Commission shall be composed of 11 members appointed or designated by the President. The members shall be distinguished individuals who have experience in such relevant disciplines as medicine, epidemiology, virology, law, insurance, education, and public health.

(b) The President shall designate a Chairman from among the members of the Commission.

Sec. 2. *Functions.* (a) The Commission shall advise the President, the Secretary of Health and Human Services, and other relevant Cabinet heads on the public health dangers including the medical, legal, ethical, social, and economic impact, from the spread of the HIV and resulting illnesses including AIDS, AIDS-related complex, and other related conditions.

(b) The primary focus of the Commission shall be to recommend measures that Federal, State, and local officials can take to (1) protect the public from contracting the HIV; (2) assist in finding a cure for AIDS; and (3) care for those who already have the disease.

(c) In particular, the Commission shall (1) evaluate efforts by educational institutions and other public and private entities to provide education and information concerning AIDS; (2) analyze the efforts currently underway by Federal, State, and local authorities to combat AIDS; (3) examine long-term impact of AIDS treatment needs on the health care delivery system, including the effect on non-AIDS patients in need of medical care; (4) review the United States history of dealing with communicable disease epidemics; (5) evaluate research activities relating to the prevention and treatment of AIDS; (6) identify future areas of research that might be needed to address the AIDS epidemic; (7) examine policies for development and release of drugs and vaccines to combat AIDS; (8) assess the progression of AIDS among the general population and among specific risk groups; (9) study legal and ethical issues relating to AIDS; and (10) review the role of the United States in the international AIDS pandemic.

(d) The Commission shall make a preliminary report to the President not later than 90 days after the date the members of the Commission are first appointed or designated. The Commission shall submit its final report no later than 1 year from the date of this Order.

Sec. 3. *Administration.* (a) The heads of Executive departments and agencies, to the extent permitted by law, shall provide the Commission, upon request, with such information as it may require for purposes of carrying out its functions.

(b) Members of the Commission may receive compensation for their work on the Commission at the daily rate specified for GS-18 of the General Schedule. While engaged in the work of the Commission, members appointed from among private citizens of the United States, to the extent funds are available, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(c) The Office of the Secretary of Health and Human Services, subject to the availability of appropriations, shall provide the Commission with such administrative services, funds, facilities, staff, and other support services as may be necessary for the performance of its functions. The heads of other Executive departments and agencies, to the extent permitted by law, shall cooperate with the Commission and provide such personnel and administrative support as may be necessary for the performance of its functions.

Sec. 4. *General Provisions.* (a) The functions of the President under the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), except that of reporting annually to the Congress, which are applicable to the Commission, shall be performed by the Secretary of Health and Human Services, in accordance with guidelines and procedures established by the Administrator of General Services.

(b) The Commission, unless sooner extended, shall terminate 30 days after submitting its final report to the President.

Ronald Reagan

THE WHITE HOUSE,
June 24, 1987.

[FR Doc. 87-14837
Filed 6-25-87; 4:14 pm]
Billing code 3195-01-M

Presidential Documents

Executive Order 12603 of July 16, 1987

Presidential Commission on the Human Immunodeficiency Virus Epidemic

By the authority vested in me as President by the Constitution and laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App. I), and in order to increase the number of members of the Presidential Commission on the Human Immunodeficiency Virus Epidemic, it is hereby ordered that Section 1(a) of Executive Order No. 12601 of June 24, 1987, is amended by changing the number of members of the Commission from 11 to 13.

Ronald Reagan

THE WHITE HOUSE,
July 16, 1987.

[FR Doc. 87-16286
Filed 7-17-87; 11:20 am]
Billing code 3195-01-M

Appendix I

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

Presidential Commission on the Human Immunodeficiency Virus Epidemic

PURPOSE

Executive Order 12601, dated June 24, 1987 established the Presidential Commission on the Human Immunodeficiency Virus Epidemic to investigate the spread of the HIV virus and the resultant acquired immune deficiency syndrome (AIDS) in the United States.

AUTHORITY

Executive Order 12601, dated June 24, 1987 as amended by Executive Order 12603, dated July 16, 1987. The Commission is governed by provisions of Public Law 92-463 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Commission was directed by the Executive Order to:

(a) The Commission shall advise the President and the Secretary of Health and Human Services, and other relevant Cabinet heads on the public health dangers including the medical, legal, ethical, social, and economic impact, from the spread of the HIV and resulting illnesses including AIDS, AIDS-related complex, and other related conditions.

(b) The primary focus of the Commission shall be to recommend measures that Federal, State, and local officials can take to (1) protect the public from contracting the HIV; (2) assist in finding a cure for AIDS; and (3) care for those who already have the disease.

(c) In particular, the Commission shall (1) evaluate efforts by educational institutions and other public and private entities to provide education and information concerning AIDS; (2) analyze the efforts currently underway by Federal, State, and local authorities to combat AIDS; (3) examine long-term impact of AIDS treatment needs on the health care delivery system, including the effect on non-AIDS patients in need of medical care; (4) review the United States history of dealing with communicable disease epidemics; (5) evaluate research activities relating to the prevention and treatment of AIDS; (6) identify future areas of research that might be needed to address the AIDS epidemic; (7) examine policies for development and release of drugs and vaccines to combat AIDS;

(8) assess the progression of AIDS among the general population and among specific risk groups; (9) study legal and ethical issues relating to AIDS; and (10) review the role of the United States in the international AIDS pandemic.

The heads of Executive departments and agencies, to the extent permitted by law, shall provide the Commission, upon request, with such information as it may require for purposes of carrying out its functions.

STRUCTURE

The Commission shall consist of thirteen members appointed or designated by the President. Members shall be distinguished individuals who have experience in such relevant disciplines as medicine, epidemiology, virology, law, insurance, education and public health. The President shall designate a Chairman from among the members of the Commission.

Members shall be invited to serve for the life of the Commission.

The Office of the Secretary of Health and Human Services, subject to the availability of appropriations, shall provide the Commission with such administrative services, funds, facilities, staff, and other support services as may be necessary for the performance of its functions.

Responsibility for management and support services shall be provided by the Office of the Secretary, Department of Health and Human Services.

MEETINGS

Meetings shall be held as often as necessary at the call of the Chairman with the advance approval of a Government official, who shall also approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary of Health and Human Services; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

COMPENSATION

Members of the Commission may receive compensation for their work on the Commission at the daily rate specified for GS-18 of the General Schedule. While engaged in the work of the Commission, members appointed from among private citizens of the United States, to the extent funds are available, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

ANNUAL COST ESTIMATE

Estimated annual cost for operating the Commission, including compensation and travel expenses for members but excluding staff support, is $950,000. Estimate of annual man-years of staff support is 8, at an estimated annual cost of $400,000.

REPORTS

The Commission shall make a preliminary report to the President not later than 90 days after the date the members of the Commission are first appointed or designated. The Commission shall submit its final report no later than 1 year from the date of Executive Order 12601.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Presidential Commission on the Human Immunodeficiency Virus Epidemic shall terminate 30 days after submission of its final report to the President.

APPROVED

This Charter is being approved by the Secretary of Health and Human Services pursuant to the authority delegated to him by the President in Executive Order 12601.

July 23 1987
Date

R. Bowen M.D.
Otis R. Bowen, M.D.
Secretary

Appendix J

GLOSSARY

affective pertaining to a feeling or mental state.

AIDS Treatment Evaluation Unit (ATEU) original name of the AIDS Clinical Trial Groups, established by National Institute of Allergy and Infectious Diseases to test new AIDS-related drugs.

AIDS Clinical Trial Group (ACTG) experimental drug testing system administrated by National Institute of Allergy and Infectious Diseases. Also, one of the 35 medical centers in the group.

animal models trials done in animals prior to human studies. For example, tests of various substances in standardized genetic strains of mice or the tests of HIV vaccine in chimpanzees.

antibody a molecule produced in response to antigen which has the particular property of combining specifically with the antigen which induced its formation.

antigen a molecule which induces the formation of an antibody.

aseptic meningitis inflammation of the membranes that envelop the brain and spinal column caused by a viral agent.

autologous transfusion blood transfusion in which the patient receives his or her own blood.

basic research research in the basic or pure sciences. Not product-oriented.

candidiasis yeastlike fungus infection. A common opportunistic infection.

clinical trials studies in human subjects.

co-factors those factors which can influence an individual's likelihood of becoming ill or influence the progression of disease. Commonly cited HIV-related co-factors include a history of intravenous drug abuse, and presence or history of sexually transmitted diseases or other immunocompromising conditions.

cohort studies studies that follow groups of similar individuals over time, noting who develops a disease and who does not, and comparing these two groups at the end of the study to determine co-factors and other elements that may influence outcome. Cohort studies of gay men in San Francisco have determined that behavior modification can influence incidence of HIV infection, and reduce the number of new cases.

crystallography the study of crystal structure. Used to study the structure of crystallized viruses.

cytomegalovirus one of a group of herpes viruses that infect man, monkeys, and rodents.

dementia general designation for mental deterioration.

DNA (deoxyribonucleic acid) basic genetic material. A nucleic acid found chiefly in the nucleus of living cells that is responsible for transmitting hereditary characteristics.

double blind trials see placebo controlled trials.

ELISA acronym for "enzyme-linked immunosorbent assay," a test used to detect antibodies against HIV.

epidemiology study of the relationships of the various factors determining the frequency and distribution of diseases in a human environment.

etiology study of the factors that cause disease.

genome the genetic "endowment" of an organism. A complete set of chromosomes.

GP 120 glycoprotein on the surface of HIV and a target for several potential vaccines.

Hodgkin's disease a chronic progressive disease of unknown etiology that is characterized by inflammatory enlargement of the lymph nodes, spleen, and often liver and kidneys.

hospice establishment or program which cares for the physical and emotional needs of terminally ill patients.

HTLV human T-cell lymphotropic virus. This is the family of viruses to which HIV belongs.

immunology the medical study of the immune system.

immunomodulators drugs which alter the state of immune system, usually to improve response.

immunosuppression artificial prevention or diminution of the immune response.

in vitro "in glass", observable in a test tube.

IND (investigational new drug) status of a drug after approval for use in clinical trials but before approval for marketing.

institutional review board (IRB) committee within a hospital or other institution through which all new research protocols and projects must pass. IRBs are comprised of physician members of each medical service, nurses, administrators, and patient representatives. They check to see consent forms are properly worded, all procedures are properly followed, etc.

intervention (in behavior modification research) those techniques or devices by which one behavior is interrupted and another, presumably healthier, behavior is instituted.

Kaposi's sarcoma a cancer or tumor of the blood and/or lymphatic vessel walls. It is a common opportunistic infection in HIV infection.

LAV (lymphadenopathy-associated virus) the name given by French researchers to the first reported isolate of the retrovirus now known to cause AIDS.

lentivirus a virus that can cross the blood/brain barrier, destroy brain tissue, and remain in the body in a chronic sub-clinical state for long periods. HIV is a lentivirus that causes forms of mental incapacity in an estimated 70 to 80 percent of patients, and end-stage dementia in many. Lentiviruses persist in the body by evading natural defense mechanisms. In animals, the chronic state is common. In this state, animals infected with a lentivirus are "carriers" and may not get sick themselves for a long time, but can transmit the virus to other animals.

look-back program program that attempts to identify recipients of blood from a donor who is later found to be HIV antibody positive.

lymphadenopathy disease of the lymph nodes.

lymphocyte white blood cells, some of which are involved in the immune response.

lymphoma any of the various cancers of the lymphoid tissue.

magic bullet in theory, a single drug that can knock out a particular malignant cell or other disorder without any toxicity.

microbiology science which deals with the study of microorganisms, including bacteria, fungi, and viruses.

molecular biology field of biology in which biological systems are analyzed in terms of the physics and chemistry of their molecular components.

monoclonal derived from a single cell.

morbidity frequency of disease occurrence in proportion to the population.

mortality frequency of number of deaths in proportion to the population.

myelopathy pathological changes in the bone marrow.

NDA New Drug Application. After clinical trials are completed, an NDA is filed with the Food and Drug Administration so that the drug may be placed in the market.

oncovirus sub-family of retroviruses that includes tumor-causing agents.

opportunistic infection an infection caused by an organism that rarely causes disease in persons with normal immune systems but attacks immunosuppressed patients. Infections common in patients with AIDS include toxoplasmosis, *pneumocystis carinii* pneumonia, cytomegalovirus, and tuberculosis.

orphan drugs drugs designated for use in diseases with annual patient incidence of 200,000 or less, or for which the company is not expected to be able to make a profit. Tax benefits and market exclusivity accompany orphan drug status.

P–3 biosafety level applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with agents which may cause serious or potentially lethal reactions as a result of exposure by inhalation. Practically, there must be special airflows and filters, an antechamber with sink, protective garments must always be worn, and nothing may be taken out of the room without being sterilized.

parenteral taken into the body other than through the digestive tract, as by intravenous or intramuscular injection.

pathogenesis the development of morbid conditions or of disease, more specifically, the cellular events and reactions and other mechanisms occurring in the development of disease.

perinatal occurring near the time of birth.

peripheral neuropathies functional disturbances and/or changes in the peripheral nervous system.

persistent generalized lymphadenopathy (PGL) a condition characterized by swollen glands that remain enlarged despite the absence of known current illness or drug use.

pharmacology science which deals with the study of the action of drugs on living systems.

placebo an inactive substance used as a control in an experiment.

placebo controlled trials clinical trials in which patients are randomized to one treatment group or another. One group of the trial participants receive the study drug and the other half receive a placebo. In double blind studies, neither the patient nor the physician knows if the patient is getting the drug or the placebo. This is done to eliminate the "placebo effect," the early positive response of almost all patients to receiving any therapy.

***pneumocystis carinii* pneumonia** opportunistic infection most frequently diagnosed in patients with AIDS. Caused by a parasite commonly present in the normal population, *pneumocystis carinii* infection is life-threatening in immunosuppressed patients.

polyclonal derived from different cells.

principal investigator lead scientist running a study or lead doctor running a clinical trial.

psychobiology interactions between body and mind in the formation and functioning of personality.

psychosocial associated with the systems of psychological support services -- often needed by persons with HIV infection.

reagent substance used in a chemical reaction to detect, examine, measure, or produce other substances. In virology, strains of HIV are reagents.

recombinant DNA DNA prepared through laboratory manipulation in which genes from one species of an organism are transplanted or spliced to another organism.

retrovirus one of a group of viruses that have RNA as their genetic code and have the ability to copy that RNA into DNA and incorporate it into an infected cell.

reverse transcriptase an enzyme produced by retroviruses that allows them to produce a DNA copy of their RNA. This is the first step in their natural cycle of reproduction.

RNA (ribonucleic acid) basic genetic material. A nucleic acid associated with the control of chemical activities inside a cell.

sero- prefix referring to blood serum.

seroconversion the initial development of antibodies specific to a particular antigen.

serologic pertaining to blood serum.

seropositive condition in which antibodies to a specific antigen are found in the blood.

seroprevalence prevalence based on blood serum tests.

serostatus condition of the blood -- infected or uninfected.

shooting gallery location where drug addicts meet to "shoot" intravenous drugs, often sharing needles.

STDs sexually transmitted diseases.

surveillance process of monitoring public health conditions such as epidemics. Passive surveillance monitors conditions through the receipt of reports; active surveillance employs investigative techniques.

syndrome pattern of symptoms and signs, appearing one by one or simultaneously that together characterize a particular disease or disorder.

T-cell cell that matures in the thymus gland. T-lymphocytes are found primarily in the blood, lymph, and lymphoid organs. Subsets of T-cells have a variety of specialized functions within the immune system.

T4 cell count measure of the state of the immune system based on the number of T4 lymphocytes present in the blood.

treatment use regulations Also: compassionate use. Process by which a drug company applies to the Food and Drug Administration, in special cases, to distribute drugs to the desperately ill even though the drug has not been approved for use outside a clinical trial. In some cases, this also applies to drugs that have been approved for use but not for the disease for which it is being requested. A change in the rules in June 1987 allowed for the release of such drugs earlier than usual for AIDS, but to date, only one has been so used.

virology study of viruses and virus diseases.

Western blot blood test that involves the identification of antibodies against specific protein molecules. This test is more specific than the ELISA test in detecting antibodies to HIV in blood samples. It is used as a confirmatory test for positive ELISA samples. The Western blot requires more sophisticated lab technique than the ELISA and is more expensive.

The Commission acknowledges the work of the National Academy of Sciences in *Confronting AIDS*, which was invaluable in the preparation of this glossary.

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